An Evaluation of Sialorrhoea Management Practices in Residential Older Adult Care Settings

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Thesis submitted in fulfilment of the requirement of Waterford Institute of Technology for the Degree of Masters of Science

Foirfe chun fónaimh

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Declaration

I, Li Ping Varley, hereby declare that this thesis is submitted for the degree of Masters of Science (MSc) and is entirely my own work except where otherwise acknowledgement has been made in the text. It has not at any time been submitted for any other educational award.

Signed: Lipingvarley (Candidate)

LI PING VARLEY

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Table 6.1 Summary of recommendations.

Abstract

An Evaluation of Sialorrhoea Management Practices in Residential Older Adult Care Settings

Presented by Li Ping Varley

Background: Sialorrhoea (drooling) is the unintentional loss of saliva from the mouth; it is a common and upsetting problem amongst people with certain neurological disorders. It can lead to complications, especially infection, dehydration and fatigue. Saliva can also collect at the back of the throat which causes coughing and may lead to a higher risk of aspiration. In addition, complications from sialorrhoea may cause psychological complications, such as embarrassment, social isolation and feelings of rejection. All these consequences of sialorrhoea can subsequently impact on quality of life. However, there is limited research available in relation to the optimal management of sialorrhoea and subsequently there is no consensus on best practice.

Aim: Therefore, the aim of this study was to evaluate practices in the management of sialorrhoea in older adult residential care settings and to, consequently, make recommendations for sialorrhoea management so as to improve quality of life and enhance the person-centred care approach to sialorrhoea management

Methods: The study adopted a two phase mixed methods design involving a cross-sectional, descriptive correlational survey and an exploratory, descriptive qualitative design. Sixteen older adult residential care settings in the South East region of Ireland were used as the study sites. A purposive sampling method was used to recruit participants in both study phases. The first phase of this study involved two concurrent strands, one strand involved a survey of older adults experiencing sialorrhoea to identify the impact of sialorrhoea regarding their care needs and their views on sialorrhoea management. The parallel strand involved focus group interviews with the multidisciplinary healthcare team involved with the care of older adults with sialorrhoea to explore and identify current sialorrhoea management practices. The second phase of this study involved one to one in-depth interviews with caregivers (nurses or healthcare assistants) in care of older adults to further explore and confirm findings from the first phase of this study, and to identify changes required to current care and management of sialorrhoea.

Findings: Phase 1 questionnaire survey findings revealed that sialorrhoea has quite a significant impact on older adults' quality of life, relationships were identified between quality of life and impact of sialorrhoea. However, both phase 1 and phase 2 findings also revealed a lack of awareness and knowledge of the underlying issues and management strategies for sialorrhoea in these older adults' residential care settings. These findings indicate the need for more structured care provision complying with the person-centred care approach. Findings identified that first line healthcare professionals strive to provide care to older adults suffering from sialorrhoea with the utmost empathy and compassion. However, findings demonstrated that first line healthcare professionals face challenges due to a lack of guidelines and, training and education provision.

Conclusion: An understructured care provision plan, and the lack of estalished coordination of care among the multidisciplinary healthcare members indicated a deficit in a person-centred care approach to sialorrhoea management within the Irish context. Therefore study findings recommend that current practices would benefit from a structured systematic care protocol regarding sialorrhoea, so as the person-centred care approach could be augmented by such protocols. These include systematic assessment of sialorrhoea, wider multidisciplinary engagement and networking, and continuous professional development training and education programmes focusing on non-invasive management techniques. In order to improve care for older adults with sialorrhoea in residential care setting, policy makers, stakeholders and researchers should work together to further develop national evidence based guidelines to direct the management of sialorrhoea, specifically to develop protocols for nurses to follow in everyday care of the older adults.

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Index of Abbreviations

ALS	Amyotrophic Lateral Sclerosis
CP	Cerebral Palsy
CRT	Controlled Randomised Trial
CSO	Central Statistics Office
CSS-MND	Clinical Sialorrhoea Scale for MND
CVA	Cerebrovascular accident
DIS	Drooling Impact Scales
DON	Director of Nursing
DSFS	Drooling Severity and Frequency Scale
ENT	Ear, Nose, Throat
GP	General Practitioner
HIQA	Health Information and Quality Authority
HSE	Health Service Executive
MDT	Multidisciplinary Team
MND	Motor Neurone Disease
OT	Occupational Therapist
PHE model	Patient Health Engagement model
PD	Parkinson’s Disease
SALT	Speech and Language therapist
SCS-PD	Sialorrhoea Clinical Scale for PD

Chapter 1: Introduction and Background

Introduction

Sialorrhoea (drooling) is the unintentional loss of saliva from the mouth and can be present in older adults with certain neurological conditions. This chapter outlines the background for this study regarding sialorrhoea management and is followed by an explanation of the organisation of the dissertation. Brief background information regarding salivation is explored in Section 1.1. Sialorrhoea and its causes are addressed in Section 1.2 and 1.3. A profile of older adults in residential care settings is provided in Section 1.4. Overall information regarding management strategies is reviewed in order to situate the study in the context of the provision of management of sialorrhoea in Section 1.5. Subsequently, Section 1.6 provides a rationale for undertaking this study, outlining the importance and relevance for older adults with sialorrhoea, residential care settings services, the multidisciplinary healthcare professionals and the academic community. The layout and organisation of the thesis is provided in Section 1.7.

1.1. Salivary glands and salivation

Saliva is produced by three pairs of major salivary glands – the parotid, submandibular, and sublingual glands, and many minor salivary glands located throughout the oral cavity (Figure 2.2; Suburban Ear, Nose and Throat Associates, 2012). The salivary glands consist of acinar and ductal cells, and saliva is secreted into the mouth through the excretory ducts within these glands. The parotid, submandibular or submaxillary, and sublingual salivary glands produce approximately 93% of the saliva (Llena-Puy, 2006).

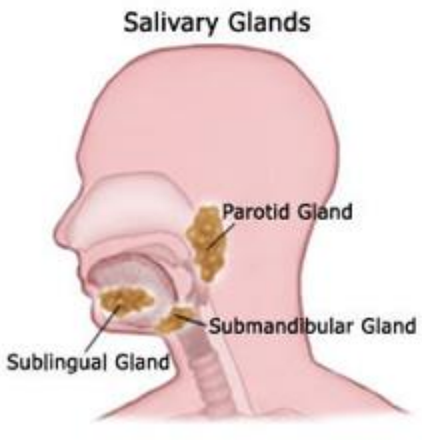


Figure 2.2. General illustration of major salivary glands (Suburban Ear, Nose and Throat Associates, 2012)

1.1.1 Parotid glands

As seen in Figure 2. 2, the parotid glands are the largest, which are located just in front of the two ears. These two glands secrete the saliva into the mouth through the parotid ducts (Stenson's ducts).

1.1.2 Submandibular Glands

The submandibular glands are the second largest; each of the glands is about the size of a walnut. They are located below each side of the jaw, and these two glands secrete the saliva into the mouth through the submandibular ducts (Wharton's ducts).

1.1.3 Sublingual Glands

As shown in Figure 2. 2, the sublingual glands are the smallest of the three pairs of the major salivary glands. They are shaped like almonds and are located under the floor of the mouth and below either side of the tongue. These two glands secrete the saliva into the mouth through the sublingual ducts (Bartholin's ducts and Ducts of Rivinus).

1.1.4 Minor Salivary Glands

Hundreds of minor salivary glands are located throughout the mouth and the aerodigestive tract. Most are found in the lining of the lips, the tongue, and the roof of the mouth, as well as inside the cheeks, nose, sinuses, and larynx/voice box (Humphrey

& Williamson, 2001). They are responsible for about 10% of saliva production (Feher, 2017).

1.1.5 Salivation

Salivary gland secretion is a compound function and is a nerve-mediated reflex regulated by the autonomic nervous system (Proctor, 2016). The salivation neural control comes from both afferent and efferent stimuli (Miranda-Rius *et al.,* 2015). Consequently, the salivation process involves afferent receptors and nerves carrying impulses induced by stimulation, in additional to a central hub (the salivary nuclei), and an efferent part consisting of parasympathetic and sympathetic autonomic nerve bundles that separately innervate the glands (Whelton, 2012). The parasympathetic nervous system innervates the major salivary glands and promotes secretion of saliva. The sympathetic nervous system controls the flow of the saliva by causing the contraction of the muscle fibres within the salivary ducts. Parasympathetic and sympathetic nerves run together to the target cells in salivary glands, and both parasympathetic and sympathetic impulses act on secretory cells simultaneously. Sympathetic nerve stimulation evokes a protein-rich secretion, whereas parasympathetic stimulation evokes a large volume of saliva (Proctor, 2016).

1.1.6 Function of Saliva

The presence of saliva is vital to the maintenance of oral health (Whelton, 2012). Saliva serves many roles. Its function can be divided into five major categories that serve to maintain oral health and create an appropriate oral ecological balance: (1) lubrication and protection; (2) buffering action and clearance; (3) maintenance of tooth integrity; (4) antibacterial activity; and (5) taste and digestion (Moss, 1995).

By keeping the mouth moist and lubricated, saliva aids in the movement of the lips and tongue both in the action of chewing and in speech (Feher, 2017). Another important role of saliva is to maintain oral hygiene; saliva contains a variety of antibacterial and antifungal components, which help prevent infections and keep the mouth clean by helping flush away food particles, and reduce dental decay in the maintenance of tooth integrity (Humphrey & Williamson, 2001).

An understanding of saliva and its role in oral health of the older adult will help to promote awareness among healthcare workers of the problems arising when the quantity or quality of saliva is changed; this awareness and understanding is important to the prevention, early diagnosis and treatment of sialorrhoea.

1.2 Sialorrhoea

Sialorrhoea occurs when saliva spills over the lips, flows outside the mouth, due to an inability to control oral secretions; or weak and infrequent swallowing; or a combination of both, leading to excessive saliva in the oropharynx (Cardoso, 2018). There are two broad categories of sialorrhoea: anterior sialorrhoea and posterior sialorrhoea. Anterior sialorrhoea refers to saliva dripping over the lip. Posterior sialorrhoea happens when saliva falls posteriorly at the top of the tongue and pools in the hypopharynx, thereby increasing the risk of aspiration (Jongerius *et al*., 2003; Lawrence & Bateman, 2018). Complications from sialorrhoea may lead to physical and socio psychological discomfort and risk.

1.3 Causes of sialorrhoea

It is clear that saliva plays a crucial role in maintaining the integrity of the oral structures, in digestion and in controlling oral infection. However, numerous physiological and pathological factors can cause variations in salivary flow (Llena-Puy, 2006). Sialorrhoea is quite often a common problem in people with certain medical conditions. The causes of sialorrhoea are multiple and complex. However, sialorrhoea is mainly the consequence of certain medications or a neurological systemic disease (Miranda-Rius *et al*, 2015).

In terms of medication, psychiatric medicine such as muscarinic agonists are parasympathomimetic and can increase cholinergic tone and cause salivary hypersecretion (Miranda-Rius *et al*, 2015). Other medications, such as tranquilizers, epilepsy drugs and anticholinesterases used in the treatment of dementia also have the side effect of sialorrhoea (Mato *et al*, 2010; McGeachan & McDermott, 2017).

Sialorrhoea can also be due to oral motor control disorder, swallowing disability, and facial–bullar muscle dysfunction (Mato *et al*., 2010; McGeachan & McDermott, 2017). Generally, increased salivation can be easily handled (Miranda-Rius *et al.,* 2015). However, when there is sensory dysfunction, or when there is anatomic or motor dysfunction of swallowing, the ability to manage saliva is hindered (Bavikatte *et al,* 2012). Often, sialorrhoea is not because of increased salivation, but due to disturbed saliva handling (Lakraj *et al*., 2013; Miranda-Rius *et al*., 2015). Therefore, sialorrhoea may present in neuromuscular diseases such as amyotrophic lateral sclerosis (ALS) and oculopharyngeal muscular dystrophy; neurodegenerative diseases such as Parkinson's disease (PD), multiple system atrophy, progressive supranuclear palsy, dementia with Lewy bodies and corticobasal degeneration, and cerebrovascular diseases (Srivanitchapoomab e*t al*., 2014; McGeachan & McDermott, 2017).

Weakness in mouth muscles, as may occur after a cerebrovascular accident (CVA) or with Bell's palsy and chronic nasal congestion may also cause sialorrhoea (McGeachan & McDermott, 2017). Among these conditions, the head down posture, reduced oral muscular control and deficits in awareness and attention all contribute to sialorrhoea. Therefore, the causes of sialorrhoea are complex and multifactorial.

1.4 Older adult residential care settings

Irish government policy supports the concept of older people remaining and being cared for in their own homes for as long as possible (Department of Health, 2013), with the emphasis on the person only going into residential care when they cannot be supported in the community (Health Service Executive; HSE, 2015b). Where it is deemed that the older adult cannot remain at home due to a physical or cognitive impairment, the option to move into residential care is then considered (HSE, 2017). Residential care refers to the long-term care that an adult receives in a residential setting as opposed to in the hospital or in the patient's home (Bri, 2015).

The majority of the older adults in residential care settings require much care and attention (Murphy *et al*., 2006) and their needs can be complex and require a significant planned and integrated care approach. The purpose of care of older adults in residential care settings is to meet older adult's needs in a manner that safeguards their dignity and wishes while ensuring best practice in medical, nursing and social care provision(Browne, 2016). Sialorrhoea, as one of the common conditions in older adults in residential care settings, can cause negative impacts upon individual's quality of life. Therefore, its management should be an important part of the care of older adults in residential care settings.

1.5 Sialorrhoea management strategies

Sialorrhoea treatment typically depends on identifying the underlying causes. However, due to the complexity of sialorrhoea causes, it is very unlikely to have one single completely effective treatment. It has been suggested that the management approach should ideally be simple, non-invasive, safe and efficient (Crysdale *et al*., 2006; Reddihough *et al.,* 2010). Therefore, a hierarchy of management approaches can be utilised from minimum invasive interventions, such as speech and language therapy, to more invasive treatments, namely, botulinum neurotoxin injection and surgery (de Bruijn *et al*., 2017).

Individuals with different causative factors may require a combination of management approaches, and the management of sialorrhoea may require multiple health care providers with different areas of expertise, including: nurses, primary care doctors/general practitioners, dentists/orthodontists, Ear, Nose, Throat (ENT) doctors, speech and language therapists, occupational therapists, physiotherapists and neurologists (Fairhurst & Cockerill, 2011; McGeachan & McDermott, 2017). It is advisable that sialorrhoea management follows such a multidisciplinary approach, on an individualised basis (Crysdale *et al*., 2006; Reddihough *et al.,* 2010), which will empower individualised care of patients by implementing specified evidence-based management plans. Therefore, this approach should lead to more effective treatment, higher satisfaction with care from patients and improved quality of life.

1.6 Rationale for this study

Within the Irish context, according to the Central Statistics Office (CSO; 2016), the population aged 65 years and over has increased by 102,174 since 2011 to 637,567 (19.1%) in 2016, with increased absolute numbers of persons aged 65 and over in nursing homes. The number of people aged 65 is predicted to rise to 1.4 million in 2046 (CSO, 2011). Approximately 6% of the population of people aged 65 years and older in Ireland are receiving residential care (McGill, 2010; CSO, 2012b). The increase in the number of people aged 65 years and older and the projected increase in life expectancy suggest that a greater number of older people will require care in the residential sector. Under such circumstances, the context of healthcare and support will need to be continuously changing as people's life expectancy increases with the number of older adults requiring support increasing also (Department of Health, 2012a).

Chronic conditions become more common with increasing age, with neurological diseases affecting between 5% and 55% of people aged 55 years and older (Hoffman *et al.*, 2013; Murray *et al.,* 2012). The prevalence of sialorrhoea in patients with neurological conditions is high and sialorrhoea can invariably cause negative impacts upon their quality of life. Sialorrhoea can be the reason for impairment of social integration and for difficulty performing oral motor activities during eating and speech, which have repercussions on quality of life (Bavikatte *et al.*, 2012). In Ireland, among these people who live in nursing homes, 1 out of 10 suffer from Parkinson's disease (PD; Parkinson's Association of Ireland, 2019). One of the common complications of PD is dysphagia leading to sialorrhoea, which can occur in up to 80% of people with PD (Kalf *et al.*, 2012). There are approximately 360 people over the age of 50 years living with motor neurone disease (MND) at any one time in Ireland (Irish Motor Neurone Disease Association, 2019), and the prevalence of sialorrhoea among patients with MND is estimated to be between 20% and 40% (Stone & O'Leary, 2009).

The prevalence of neurological disorders among older adults, along with the associated issues with sialorrhoea poses a need to assess the current practice of sialorrhoea management in the older adult care setting in order to provide the best possible care.

Research studies have been carried out internationally identifying various sialorrhoea management approaches, however, within the Irish context, there have been limited evidence-based management protocols established. Very few studies have been carried out to guide optimal management of sialorrhoea and there is no consensus on best practice to minimise the negative impact of sialorrhoea for the individuals with the condition. Therefore, this research endeavoured to examine how sialorrhoea is managed in residential care settings, with the intention of identifying an effective management approach. It was anticipated that the research findings would raise cognisance of the impact of sialorrhoea on patients and be formative in enhancing optimum care of sialorrhoea.

1.7 Organisation and layout of the thesis

This thesis is organised into six chapters.

Chapter 1 Introduction: provides an overview of the entire study, introduces the research study, positions the research study within the Irish context and offers a justification for the research. The background and rationale for the research study is also provided.

Chapter 2 Literature Review: provides a critical account of the literature, and focuses on the empirical evidence currently available regarding sialorrhoea; the signs and symptoms, causes, prevalence; assessments of and treatment options including the multidisciplinary management approach. Firstly, an outline of the search strategy and the scope of the review are provided. The literature in relation to the causes of sialorrhoea, the impact and the assessment of the impacts involved is critically analysed. In addition, the studies regarding different management approaches are explored and the role of the care providers involved in the provision of residential care services for older adults is presented. Finally, multidisciplinary management approaches are explored in order to understand what processes and barriers are involved in accessing multidisciplinary healthcare services in care of sialorrhoea.

Chapter 3 Methodology: outlines the research design, sampling method chosen, recruitment procedures and instruments utilised for objective and subjective data collection. It presents the research aims and objectives along with the philosophical underpinnings of the mixed methodological framework used to guide the research design. The methods of data collection and the methodological processes are described, the types of data analysis used in the different phases of the research study design are outlined and are discussed in relation to impact on the overall outcome of the research project.

Chapter 4 Results: presents the findings from each phase of the study in line with the study objectives.

Chapter 5 Discussion: presents the integration of findings from all phases of the research with the literature findings. The importance of this research study is discussed in light of person-centred sialorrhoea management approaches in Ireland.

Chapter 6 Conclusion: provides an overall conclusion to the study. The clinical significance and relevance of the study are explored with suggestions for future research identified. It discusses the strengths, weaknesses, opportunities of the research study. Recommendations for practice and service development are discussed. The contribution of this study is discussed in relation to the research literature, clinical practice, healthcare professional education and policy within the Irish context.

1.8 Conclusion

This first chapter has introduced the thesis, providing the background, the rationale and justification behind this study. The need to explore best sialorrhoea management practice was highlighted. Finally, the structure of the thesis was outlined.

Chapter 2: Literature Review

Introduction

This chapter provides a background for the research study through an extensive literature review. The aim of this literature review was to evaluate the evidence and to identify gaps in relation to the current provision of sialorrhoea management in the care of older adults. Firstly, an outline of the literature search strategy is provided in Section 2.1. 2.2 explore the prevalence of sialorrhoea. Section 2.3 reviews the impact of sialorrhoea on patients: physically, emotionally, and socially. Different tools used in the assessment of the severity and frequency of sialorrhoea are explored in Section 2.4. The characteristics of different management approaches are identified in Section 2.5 and 2.6. The Person-centred care approach is explained in Section 2.7. Brief literature critique is provided in Section 2.8. The literature review is concluded by Section 2.9, which focuses on the multidisciplinary (MDT) management approach in order to further inform this study.

2.1 Literature search strategy

The literature search was conducted using five databases: Science direct, Wiley online library, CINAHL, Cochrane library and PubMed. The websites Google and Google Scholar were also used to extend the literature search. The library within Waterford Institute of Technology was utilised for an extensive search of books and articles. A combined free-text and thesaurus approach was adopted using both UK and US spellings for key-word selection with mesh terms: Drooling' or 'Sialorrhea/sialorrhoea' and 'older adults', Drooling' or 'Sialorrhea/sialorrhoea' and 'management' and 'older adults', 'Drooling' or 'Sialorrhea/sialorrhoea' and 'treatment' and 'older adults', 'Drooling' or 'Sialorrhea/sialorrhoea' and 'intervention' and 'older adults', 'Drooling' or 'Sialorrhea/sialorrhoea' and 'therapy' and 'older adults'. In addition, reference lists in retrieved publications were reviewed. Predefined inclusion and exclusion criteria were utilised in order to ensure as many relevant papers as possible were identified. The inclusion criteria included original study papers and peer reviewed papers written in the English language, which focus on sialorrhoea management, intervention, treatment, prevalence, assessment and impact on patient’s quality of life. There was no time limit set for the publication dates for the initial search in order to gain broad knowledge of the research area. The inclusion criteria also included books and other material where relevant to the terms of the search. The exclusion criteria included papers that did not address any of the inclusion criteria (See Table 2.1).

Table 2.1: Inclusion and exclusion criteria for literature search.

Inclusion Criteria	Exclusion Criteria
• Studies that address the topic of sialorrhoea management, in the area of its effectiveness and side effects of different management strategies. • Papers that address sialorrhoea assessment, prevalence, and validation of assessment tools. • Reviews, conference papers, books addressing sialorrhoea. • Papers must be of original design, peer reviewed, and in the English language.	• Non –English language papers

Figure 2.1 below displays the process of the literature search, study identification and screening process. In excess of 568 studies were considered potentially relevant to the review. The screening of identified studies involved three steps. First step: assessment of the study title. Second step: assessment of the abstracts. Third step: assessment and review of full-text of the studies. This resulted in a final selection and appraisal of the full text of 106 papers.

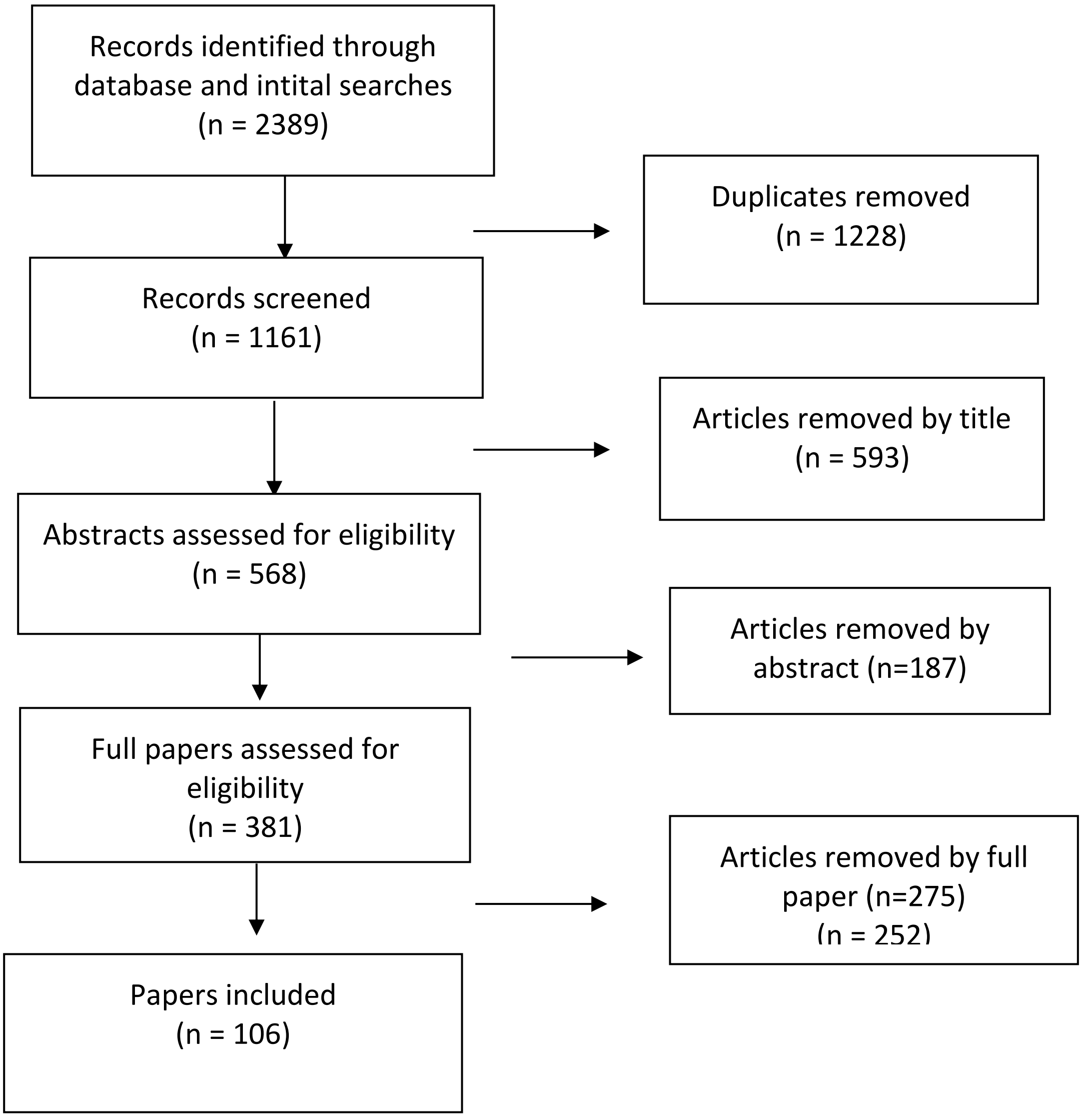


Figure 2. 1. PRISMA Flow Diagram (Moher et al., 2009)

The results of this search include 46 original studies regarding impacts of sialorrhoea and management approaches in addition to 60 review papers in relation to impacts, causes, prevalence and assessment of sialorrhoea.

2.2 Sialorrhoea prevalence among the adult population

Although there is limited data concerning sialorrhoea prevalence rates in the literature, some authors have provided information on this. Miranda-Rius *et al.* (2015) reported a sialorrhoea prevalence of 56% in PD whilst Jongerius *et al.* (2004) estimated a higher prevalence among PD, at 70%. Srivanitchapoom *et al*. (2014) estimated that the prevalence of sialorrhoea in PD is 10%-84%, whilst Stone and O'Leary (2009) estimated a prevalence of 20%-40% in MND. Giles *et al*. (2008) reported that about one in two patients with MND suffered from sialorrhoea, and of those, one in five needed continuous saliva elimination. Blackhall (2012) also stated that about half of ALS patients had significant experiences of sialorrhoea at some point during the course of their disease.

These figures indicate that sialorrhoea is a significant problematic issue, therefore, there is an urgency to investigate and to raise awareness of the importance of managing sialorrhoea effectively and efficiently.

2.3 Impact of sialorrhoea on quality of life

It seems that sialorrhoea, as a complication of certain medical conditions, and its impact on patient's quality of life has not been fully addressed. Both anterior and posterior sialorrhoea may pose physical and social risks (Dias *et al*., 2017; Garuti *et al*., 2019) and consequently, may negatively impact on the patient's quality of life. Physical consequences of sialorrhoea include excoriation of the skin around the mouth, speech and sleep disturbance, dehydration and increasing fatigue (Bavikatte *et al*., 2012). Anterior sialorrhoea may lead to peri-oral skin irritation and infection, which contributes negatively to patient's appearance and could lead to the development of psychological stress and social embarrassment (Kok *et al.,* 2016; Dias *et al*., 2017). Social embarrassment and social withdrawal will in turn contribute to low confidence and self-esteem decreasing quality of life (Chaleat-Valayer *et al*., 2016; Kok *et al*., 2016; Dias *et al*., 2017; Garuti *et al*., 2019). Studies carried out by Lloret *et al*. (2007) with 39 PD patients (Mean age 65.4±1.4), Leibner *et al*. (2009) with 59 PD patients (Mean age 69.27±SD5.17) and McGeachan *et al*. (2015) with 50 MND patients (Median age 65) identified that sialorrhoea led to skin lesions, impaired speech and eating, as well as social embarrassment while attending social activities leading to social isolation.

Sialorrhoea may also impair masticatory function, interfere with speech and eating, and result in loss of fluid, electrolytes, and proteins (Meningaud *et al*., 2006). In many patients with neurological disease, these symptoms will be accentuated by muscle weakness or dystonia in the neck, trunk or limbs causing a flexed posture and/or difficulties maintaining oral hygiene, causing unpleasant odour and tooth decay (Chaleat-Valayer *et al*., 2016).

On the other hand, saliva may also pool at the back of the throat (posterior sialorrhoea), causing coughing and a higher risk of aspiration contributing to the sensation of choking and anxiety, which may cause lung injury and respiratory complications (Jongerius *et al*., 2003; Lawrence & Bateman, 2018; Pellegrini *et al.*, 2015; Dias *et al*., 2016). In patients with ALS or MND, the risk of aspiration pneumonia is increased by the presence of secretions in the throat and bronchial tree and by the inability of the patient to perform an effective cough because of respiratory muscle weakness (Blackhall, 2012). Wolf *et a*l. (2017) analysed 200 ALS patients and found that 9.6% of these patients died from pneumonia, which might have been caused by posterior sialorrhoea.

There are also reports of pooling of saliva affecting patient’s ability to use non-invasive ventilation (NIV), which is an intervention in neuromuscular diseases that improves the quality of life and survival rates (Hadjikoutis & Wiles, 2001; Vandenberghe *et al*., 2013; Sancho *et al*, 2014). Therefore, tolerance of non-invasive ventilation, a key component of ALS care, may depend on successful control of sialorrhoea (Volanti *et al.,* 2011).

Gibbons *et al*. (2019) carried out a study with a group of 41 PD patients in the UK assessing their quality of life and reported that sialorrhoea does have a significant impact on quality of life. Furthermore, Nobrega *et al*. (2008) carried out a pilot study in Brazil with 19 PD patients and suggested that an underestimated consequence of sialorrhoea was silent aspiration which may increase the risk of respiratory infection, and hence reduce quality of life. Apart from these physical consequences of sialorrhoea, the stigma and difficulties with communication, mobility and activities of daily living, indicated greater impairment in quality of life for patients experiencing sialorrhoea compared with patients without sialorrhoea (Ou *et al*., 2015).

All these elements can be highly distressful and reduce quality of life for the patients. The risk of social rejection and physical discomfort adds further burden to the special attention required by these patients.

2. 4 Sialorrhoea assessment and measurement

In order to understand the severity of sialorrhoea and monitor the effectiveness of treatment, it is essential to assess its timing, severity and frequency as well as its impact on patient's life (Fairhurst &Cockerill, 2009; Reddihough et al., 2010; Bavikatte *et al*., 2012; Güvenç, 2018).

There have been objective and subjective measures developed to quantify sialorrhoea. Historically, sialorrhoea had been measured by using radioactive isotopes (Ekedahl & Hallen, 1973) for quantitative measurement or with collection units such as urine or suction bags (Sochaniwskyj, 1982). However, these methods are complicated and quite invasive, and leakage can be a problem (Dias *et al*., 2016; Reid *et al.,* 2010). Another limitation is that these tools developed to measure the volume of saliva and salivary flow are time-consuming and do not evaluate the psychosocial impact (Srivanitchapoom *et al*., 2014). Lately, subjective assessment tools have been developed to record the views of the caregivers or patients concerning sialorrhoea (Van der Burg *et al*., 2006). A summary of these can be seen in table 2.2.

Table 2.2 Summary of sialorrhoea assessment tools

Measure	Author	Number of items	Response type	Scoring range	Reliability and Validity
Drooling Severity and Frequency Scale (DSFS)	Thomas-Stonell and Greenberg (1988)	2	Severity and frequency	2-9	These scales are useful in assessing and monitoring therapy, however, it doesn't address any social and emotional impact which patients experience (Reid *et al*., 2010)
Teacher Drooling Scale (TDS)	Camp-Bruno (1989)	1	Frequency	1-9	The results of the Teacher Sialorrhoea Scale need to be interpreted cautiously.Since not all teachers perceive or pay the same amount of attention to the participant's sialorrhoea, depending on the class environment (for example, number of students, disposition of the class, needs of other students.) (Sénécal, 2012)
Bib weighing/number of bib changes	Bothwell *et al*. (2002)	I	Weight of dental bibs after 5-10 minutes of wear.	N/A	In spite of some support evidence of the validity of this approach, the process is prone to measurement error coming from evaporation, possibly other liquids being spilled on the bib, or saliva missing the bib (Rashnoo & Daniel, 2015)
Roll saturation testing	Ellies *et al*. (2002)	1	Dental rolls are placed into mouth for 5 minutes to obtain salivary flow rate.	N/A	It is a non-invasive procedure to quantify the volume of produced saliva, however, it can't measure the amount of saliva beyond the margin of the lower lip (Jongerius *et al*., 2003)
Drooling Rating Scale	Suskind *et al*. (2002)	5	Quality of life, physical, drooling quotient and caregiver issues.	0-15	This has been useful for discriminating between children in terms of the severity and frequency of sialorrhoea, but it has not proved to be responsive to clinically significant change after interventions (Reid *et al*., 2008)

Table 2.2 Summary of sialorrhoea assessment tools (continued)

Measure	**Author**	**Number of items**	**Response type**	**Scoring range**	**Reliability and Validity**
Sialorrhea Clinical Scale for PD (SCS-PD)	Lloret *et.al*. (2007)	7	Impact on social and physical quality of life	0-21	It is mainly designed for adult patients with Parkinson disease.
Oral Secretion Scale (OSS)	Cazzolli *et al*. (2010)	2	Saliva retention and swallowing capacity.	0-4	It is specifically designed for the evaluation of sialorrhoea in ALS patient.
Drooling Impact Scale (DIS)	Reid *et al*. (2010)	10	The impact of sialorrhoea in children.	0-100	This subjective method was only designed for the evaluation of changes in sialorrhoea in children.
Visual Analogue Scale(VAS)	Scheffer *et al*. (2010)	1	The extent of sialorrhoea on a 10 cm line.	0-100	There is no evidence of validation of this procedure (Srivanitchapoom,2014)
Drooling Quotient (DQ)	Van Hulst *et al*, (2012)	1	Sialorrhoea in three separate periods, before, during and after intervention.	0-60	The differences in saliva quantity cannot be measured accurately due to the fact that the volume of stringy drool is greater than saliva drops. It requires long period of measurement in order to achieve an accurate sialorrhoea severity score regarding the variability of sialorrhoea severity throughout the day (Reid *et al*, 2012)
Clinical Saliva Scale for MND (CSS-MND)	McGeachan *et al*. (2015)	9	social and physical quality of life	0-27	It is used to reflect the impact of sialorrhoea on adults with motor neurone disease.

Thomas-Stonell and Greenburg (1988) created the ‘Drooling Severity and Frequency Scale’ (DSFS; Appendix R) for subjective assessment of sialorrhoea. Patients, parents or carers are asked to rate the severity and frequency of sialorrhoea via a questionnaire survey. In this scale, Drooling Severity is given a score ranging from one to five, and the Drooling Frequency score ranges between one and four. It gives an impression regarding the dimensions of sialorrhoea and can be used for studying outcomes. The ordinal scale makes it useful for statistical purposes (Reddihough *et al*., 2010). It has proven to be an effective and useful measurement, and subsequently, this method has been adapted in other subjective measurement scales (see Table 2.2), such as the Visual Analogue Scale (VAS), the Drooling Rating Scale (DRS) and the Teacher Drooling Scale (TDS).

The DSFS is an easy and comprehensive scale; therefore, it is easy to administer and has been widely used although its reliability has never been tested. From the literature, DSFS has been used to measure sialorrhoea in both children and adults (Santamato *et al.,* 2008; Mato *et al*., 2010; Parr *et al.,* 2014; Assouline *et al*., 2014).

These scales are easy to apply and useful in assessing and monitoring therapy. However, there is no assessment of the social and emotional impacts which patients may experience (Reid *et al*., 2010; Srivanitchapoom *et al.*, 2014). In 2010, Reid *et al*. created the ‘Drooling Impact Scales (DIS)’, which uses a ten-point scale. This questionnaire-based method includes questions related to impacts of sialorrhoea on physical, quality of life, and caregiver issues (Evatt *et al*., 2009; Reid *et a*l., 2010). However, this DIS is mainly used for assessing the quality of life among children.

In order to assess the quality of life among adults with sialorrhoea, Lloret *et al*. (2007) created the ‘Sialorrhea Clinical Scale for Parkinson’s disease’ (SCS-PD; Appendix P). The SCS-PD uses a four-point scale to assess how sialorrhoea affect people’s social and physical quality of life (Srivanitchapoom *et al*., 2014), it assesses social and functional impairment with respect to the severity and frequency of sialorrhoea. Based on the SCS-PD, McGeachan *et al*. (2015) created the ‘Clinical Saliva Scale for motor neurone disease’ (CSS-MND; Appendix Q), which is an add-on from the SCS-PD including two extra items to assess the impact of coughing as a result of excessive saliva spilling into the patient’s throat and the impact of excessive saliva on the use of non-invasive ventilation (NIV). These scales are a patient-reported measure for the impact of sialorrhoea (Pellegrini *et al*., 2015).

Often, authors might use a combination of assessment tools to evaluate treatment outcomes from different aspects. Parr *et al*. (2014) used the DSFS and DIS to measure the efficacy of glycopyrronium and hyoscine on sialorrhoea in children with neurodisability. Mato *et al*. (2010) used the DSFS and number of bibs to evaluate the management of sialorrhoea in patients with Scopolamine patches. Leibner *et al*. (2010), Kalf (2012) and McGeachan *et al*. (2015) used the SCS-PD/CSS-MND to measure sialorrhoea severity and management as well as an evaluation of sialorrhoea burden. Although the SCS-PD was initially designed for PD patient, McGeachan *et al*., (2015) adapted it by adding extra items and created the CSS-MND to assess sialorrhoea in adults with MND. In this case, the CSS-MND may still be suitable for assessing sialorrhoea impact on adults experiencing sialorrhoea due to other medical conditions. Therefore, the DSFS and the SCS-PD/CSS-MND may be the most appropriate tools to assess older adults' sialorrhoea management in this study.

2.5 Sialorrhoea management approaches

Generally, the focus of sialorrhoea management is to reduce salivary flow rate, reduce risks of lung infection and other infections, and to improve social interaction (Chaleat-Valayer *et al*, 2016). Depending on the severity of sialorrhoea, the treatment and management options include both conservative/non-invasive and invasive approaches.

The non-invasive approaches includes interventions such as speech therapy and physiotherapy programs, biofeedback, and postural change. Invasive procedures include medication, radiation, Botulinum toxin injection, and surgery (Dand & Sakel, 2010; Daniel, 2012; Schroeder *et al*., 2012).

However, with a vast array of sialorrhoea treatment options, there is lack of a single, universally accepted treatment (Daniel, 2012). Furthermore, there is no clear consensus on which interventions are safe and effective in managing sialorrhoea (Walshe *et al*., 2012), as this can vary from patient to patient depending on their specific needs.

Therefore, an initial diagnosis of the problem must be established, with identification of the implicated factors in each case. Due to the complexity of patient's neurological conditions, the management approach is to be followed by an individualised treatment plan that should be as non-invasive as possible. The National Institute for Health and Care Excellence (NICE; UK, 2017) provides recommendations on the managements of sialorrhoea for patients with PD. These include only considering pharmacological management if non-pharmacological management such as speech and language therapy is not available or has not been effective, consider referral to a specialist service for botulinum toxin following anticholinergic treatment which is not effective, not tolerated, contraindicated or if it is having adverse effects.

Therefore, it is advisable that sialorrhoea management follows a multidisciplinary approach, on an individualised basis (Crysdale *et al*., 2006; Reddihough, 2010; Silvestre-Rangil *et al*, 2011). This individualised treatment plan should also follow a hierarchical approach arranging from least invasive therapies, such as speech pathology, to more invasive treatment, such as injection of botulinum neurotoxin and surgery (Lal & Hotaling, 2006; de Bruijn *et al*, 2017). Subsequently, the management of sialorrhoea may require multiple health care providers with different expertise, including nurses, primary care doctors, dentists, ENT doctors, speech and language therapist, and neurologists (Chávez *et al*., 2008; Fairhurst & Cockerill, 2011; McGeachan & McDermott, 2017).

2.5.1 Non-invasive management of sialorrhoea

Non-invasive management is generally the first-line management choice (Pellegrini *et al*., 2015; McGeachan & McDermot, 2017). Identified studies (see Appendix 1) regarding non-invasive management were conducted in different countries, and were carried out by different professionals, including speech and language therapists, dentists, and physiotherapists. The majority of studies reviewed focused on a combination of behavioural interventions, for instance, cuing, prompting and reinforcement techniques (Marks *et al*., 2001; Lamncioni *et al.,* 2009; Van der Burg *et al*., 2009; Lamncioni *et al*., 2011; de Bruijn *et al.,* 2017). These behavioural interventions aim to increase target behaviours such as swallowing, wiping, head control, mouth closure, and eliciting self-control of sialorrhoea behaviour (Van der Burg *et al*., 2007).

Reinforcement was widely used in studies with children (Marks *et al*., 2001; Van der Burg *et al.,* 2009; Lamncioni *et al.,* 2011; de Bruijn *et al.,* 2017). Apart from verbally prompting, studies also used cuing via visual, auditory or vibratory stimulus using technological devices to induce the correct response (Marks *et al*., 2001; Lamncioni *et al.,* 2009; Lamncioni *et al*., 2011). Marks et al., (2001) used a brooch style device that emitted a beep to remind the wearer to swallow at regular intervals. In the study carried out by Lamncioni *et a*l. (2011), participants were assigned to wear special napkins that would be activated and produce stimulation when the person turned and pushed them up against their mouths and chins, the special device in the napkin would activate beeps as stimulation.

Some studies used oro-facial regulation therapy which employed functional intraoral appliances to increase the ability to stabilise the jaw, better tongue movement for swallowing, and lip closure, and to reduce or even eliminate sialorrhoea (Johnson *et al*., 2004; Marinone *et al*., 2017). There was, however, a high dropout rate in some studies due to the intolerance of the intraoral appliance. For those who completed the study, there was no significant change in the frequency of sialorrhoea, although the sialorrhoea severity scores were improved greatly (Johnson *et al.*, 2004). One study tried to increase tongue movement to reduce sialorrhoea (Inal *et al*., 2017), again, however, no improvement was found in the frequency of sialorrhoea.

Each study reviewed aimed to reduce sialorrhoea frequency and severity, and each reported a positive result relating to the decrease of sialorrhoea, however, none with sufficient long-term effects. All the studies reviewed suggested that these therapies, especially behavioural, self-management therapies need to be long term interventions due to the reduction of the effect after the treatment finished (Marks *et al*., 2001; Lamncioni *et al*., 2009; Van der Burg *et al*., 2009; Lamncioni *et al*., 2011; de Bruijn *et al*., 2017).

Therefore, to conclude, non-invasive management requires more consistent and longitudinal support and is, therefore, time consuming, which might be a challenge for practice areas, Chaleat-Valayer *et al*. (2016) conducted a survey of professionals (*n*=75) (mostly physical and rehabilitation medicine (PMR) specialists, ear nose and throat (ENT) specialists and paediatricians and neuro-paediatricians) who worked with patients who presented with sialorrhoea and the results demonstrated that although the majority of professionals prescribe non-invasive management therapies, only 25% prescribe them in consistent manner. Although findings from studies revealed positive outcome of non-invasive management techniques, authors still proposed further studies in relation to non-invasive approaches of sialorrhoea management (Lamncioni *et al*., 2009; Van der Burg *et al*., 2009; Lamncioni *et al*., 2011; de Bruijn *et al*., 2017). Therefore, non-invasive approaches alone might not be effective in the management of sialorrhoea. Van der Burg *et al*. (2006) proposed that non-invasive therapies such as behavioural therapy should be supported by medical interventions.

2.5.2 Invasive treatments

Invasive procedures include anticholinergic drugs, botulinum toxin injection, radiotherapy and surgery. Studies identified that examined these procedures can be seen in Appendix A.

2.5.2.1 Anticholinergic drugs

A variety of anticholinergic drugs are used to manage sialorrhea, such as hyoscine, scopolamine, glycopyrrolate/glycopyrronium, tropicamide, atropine sulfate and ipratropium bromide (Thomsen *et al.,* 2007; Mato *et al.,* 2008; Arbouw *et al*., 2010; Lloret *et al.*, 2011; Zeller *et al*., 2012; Odachi *et al*., 2017; Dias *et al.,* 2017; Parr *et al.*, 2018;). Studies confirmed the effectivness of systemic anticholinergic drugs (Mato Montero *et al.,*2008; Arbouw *et al.*, 2010; Lloret *et al.*, 2011; Zeller *et al.,* 2012Odachi *et al.*, 2017; Parr *et al.*, 2018). However, side effects of these drugs have been broadly reported, with approximately 10% to 50% of patients suffering from side effects after treatment with anticholinergic drug (Mato *et al*., 2010; Zeller *et al*., 2012; Dias *et al*., 2017; Parr *et al*., 2018). These side effects include dry mouth, skin reaction to patches, hyperactivity or change of behaviour, sleep disturbance, conspitation, and urinary retention (Mato *et al.,* 2009; Zeller *et al*., 2012*;* Dias *et al.,* 2016*;* Odachi *et al*., 2017*;* Parr *et al*., 2018). Several authors reported pupil dilatation (Mato Montero *et al*., 2008; Odachi *et al*., 2017 ;Parr *et a*l., 2018), and others reported side effects such as confusion (Odachi *et al*., 2017). Some children had to discontinue their treatment with hyoscine patches due to skin reaction to the patch adhesive (Mato *et al.,* 2010; Parr *et al.*, 2018).

Although there was no report of any significant side effects from anticholinergic drugs (Thomsen *et al.,* 2007; Arbouw *et al.*, 2010; Lloret *et al*., 2011; Odachi *et al*., 2017), overall, there was no significant improvement in sialorrhoea compared with the placebo group *(*Arbouw *et al.*, 2010; Lloret *et al*., 2011*;* Odachi *et al*., 2017*).* Therefore, further research is required in order to identify an effective anticholinergic treatment option for sialorrhea management with less side effects.

2.5.2.2 Botulinum toxin injection

Both Botulimum toxin (BoNT) A and B are used for the treatment of sialorrhoea, it has been shown to have fewer side effects than anticholinergic medication while also decreasing the risk of aspiration pneumonia in people with neurological disease (Faria *et al.,* 2015). Studies show that Botulimum injection is tolerable and effective in the management of sialorrhea (Jongerius *et al*., 2004; Mancini *et al*., 2003; Lagalla *et al*., 2006; Reid *et al*., 2008; Martínez-Poles *et al*., 2018; Jackson *et al*., 2009; Tiigimäe-Saar *et al*., 2018). However, BoNT has some side effects which relate to trauma at the injection site as well as adverse effects associated with the botulinum toxin, such as dry mouth, thickened bronchial secretion and viscous saliva, and diffculty chewing (Mancini *et al*., 2003; Jongerius *et al.*, 2004; Lagalla *et al*., 2006; Reid *et al*., 2008; Jackson *et al.*, 2009; Martínez-Poles *et al.*, 2018). Adverse effects relating to trauma at the site of the injection can include pain, haematoma, intraoral blood, swallowing difficulty associated with swelling of the salivary gland, infection and possible trauma to the facial nerve when injecting the parotid gland (Reddihough, 2010). One author recommended patients should be under a dentist's care due to the change of oral microflora following the injection (Tiigimäe-Saar *et al.*,2018).

Although studies confirmed BoNT's effectiveness, the maximal response was seen at one month and its effect only lasts for approximately 3-6 months (Reid *et al*., 2008).

Therefore it requires adminstration on a recurrent basis. The repeat injection may lead to antibody formation and fading efficacy (Moller *et al.,* 2015), and the sialorrhoea also reverts slowly as the toxin effect wears off (Intiso & Basciani, 2012). Another side effect, although very rare, is that it can sometimes cause dysphagia (Layton, 2014). As BoNT injections provide only short-term relief from sialorrhoea, repeated injections are unlikely to be a permanent solution.

2.5.2.3 Radiotherapy

Radiotherapy is another sialorrhoea management option. Radiotherapy to the salivary glands, either once or in divided fractions was performed on patients with MND (Andersen *et al*., 2001; Harriman, 2001; Stalpers & Morse, 2002; Neppelberg *et al.,* 2007; Cleary *et al*., 2011). Several studies reported short-term reduction in sialorrhoea (Andersen *et al.,* 2001; Harriman, 2001; Stalpers & Moser, 2002), however, side effects of pain and dry mouth were reported (Andersen *et al*., 2001; Cleary *et al*., 2011) as well as mild nausea and inflammation (Clearly *et al*., 2011). Steenbakkers *et al*. (2018) performed radiotherapy on PD patients and found that radiotherapy was effective in reducing sialorrhoea, however sticky saliva was reported. Studies demonstrated that radiotherapy required long term intervention, however, sometimes, long-term control of sialorrhoea was difficult to evaluate as the participants entered in the study could be very ill and their life expectancy was very short (Young *et al*., 2011). However, as compared with other management approaches, radiotherapy has fewer side effects, albeit it a shorter duration of effect (Banfi *et al*., 2015). Because of the small number of published studies which were only conducted on patients with PD and MND, there has been no evidence regarding the radiotherapy approach in other medical conditions, therefore, it is not possible to draw firm conclusions about its effectiveness.

2.5. 2.4 Surgery

Surgery is usually reserved as a last resort. It appears that patients undergo surgery following continued symptoms of profuse, persistent anterior sialorrhoea even after the maximal conservative or pharmacological treatment (Delsing *et al*., 2016; Lawrence and Bateman, 2018). Surgical intervention aims to either reduce or eliminate neural stimulation to the salivary glands. The underlying principle of the surgical intervention is to redirect saliva by rerouting salivary flow, to block salivary flow and induce atrophy of the glands through ligation, or eliminate the production of saliva by excising the salivary glands (Reed *et al*., 2009; Osorio *et al.,* 2009). Generally surgeriy is carried out on children with CP (Stern *et al.*, 2002; Puraviappan *et al.,* 2007; Stamataki, *et al.*, 2008; Khadivi *et al.*, 2013; Kok *et al.*, 2016;Khan *et al.*, 2016).

Studies have demonstrated that surgical management of sialorrhea is effective (Stern *et al.*, 2002; Puraviappan *et al*., 2007; Stamataki *et al.*, 2008;Khadivi *et al.*, 2013; Kok *et al.*, 2016; Khan *et al.*, 2016). Unfortunately, apart from children with CP, there has been very few clinical studies based on patients with any other sialorrhoea related neurological disorders in the literature. Side effects were also reported, such as ranula, sialoadenitis, transient swelling of the mouth floor, pneumonia and operative urinary rentention (Puraviappan *et al*., 2007; Khadivi *et al.,* 2013; Kok *et al.,* 2016; Khan *et al.*, 2016;). Some studies also reported other side effects such as dry mouth and dental decay (Stern *et al.*, 2002). Retrospective studies have indicated that there is some gradual return of sialorrhea post surgery (Stamataki *et al.*, 2008*;* Khan *et al.*, 2016). Although evidence regarding the outcomes of surgical sialorrhoea management is of low quality and varied, the majority of patients still experience subjective improvement after surgey, with reports of postive improvement in social interaction, in addition to increased self-esteem levels (Kok *et al.*, 2016). However, in current practices, there is a lack of data comparing the impact of sialorrhoea on life before and after surgery (Kok *et al.,* 2016). Data related to success and caregiver satisfaction following surgery are variable (Delsing *et al.,* 2016).

2.5.2.5 Summary of management approaches

Although there is wide range of management techniques, and there has been data to support the positive outcomes of these treatment techniques, it seems, however that no one approach provides an ideal managment protocol. Behavourial interventions have significant relapse rates due to the high levels of motivation and time required (Lawrence and Bateman, 2018). In order to benefit from behavioural and motor oral therapy, patients need to have sufficient cognitive and oral motor capacities (Kok *et al.,*2016; Van der Burg *et al*, 2009). Of note, there have been no comparative trials undertaken regarding the effectiveness of behavioural interventions and commonly used medications (Fairhurst and Cockerill, 2011).

Anticholinergic drugs such as benztropine, glycopyrrolate and scopolamine have been used as first line medication in the management of sialorrhoea. Although, studies prove their effectiveness, these drugs often cause problematic adverse effects, their long-term effectiveness remains unknown (Mato *et al,* 2010) and there are insufficient data regarding safety (Seppi *et al*., 2011; Srivanitchapoom*et al.,* 2015). The side effects of these drugs have been broadly reported, such as dry mouth, which might be more stressful, as dry mouth may cause poor oral hygiene (Prommer, 2013). There is also a lack of evidence about which anticholinergic medication might provide the best balance between effectiveness and adverse side effects. Limited research has been conducted across a range of diseases and the supporting evidence of the effectiveness of these drugs is limited.

One of the common adverse effect of BoNT is mild dryness of mouth. Therefore, the effectiveness and low rate of side effects indicate that injection of BoNT-A and BoNT-B into salivary glands is an effective way of treating sialorrhoea. However, the effect generally lasts only 3 to 6 months, and the repeat injection may lead to antibody formation and fading efficacy (Moller *et al.,* 2015). Therefore, sialorrhoea also reverts slowly as the toxin effect wears off (Intiso & Basciani, 2012). Therefore, BoNT injection is not a long term solution of sialorrhoea management. Furthermore, there is still a dearth of universally agreed guiding procedure regarding using BoNT to manage sialorrhoea.

Surgical procedures are shown to be effective, with minimalsied adverse effects. As its effect is irreversible, surgery generates considerable controversy. From published studies, the surgical interventions were mostly performed on children with CP. There are no clinical studies on patients with ALS or any other sialorrhoea related neurological disorders in the literature. And there are some areas of uncertainty that need further research including its safety and effectiveness. Therefore, further high-level quality evidence to assess the indications, patient selection, effectiveness and safety of all the aforementioned management techniques is still required to further improve individual patient outcomes.

2.6. Multidisciplinary approach to sialorrhoea management

It is clear from reviewing these studies, that, a multidisciplinary approach is essential for appropriate assessment and management of sialorrhoea (Meningaud *et al*., 2006; Bavikatte *et al.,* 2012). Despite being associated with poorer quality of life, sialorrhoea is still an under recognised and poorly treated symptom (Morgante *et al.*, 2019). Van der Marck *et al*. (2013) carried out a randomized controlled study with 122 PD patients (n=112) and reported positive findings with a MDT care approach. Multidisciplinary evaluation and management are time consuming, but it is a very appropriate way to manage sialorrhoea due to the fact that many patients may have many different issues or challenges (Crysdale *et al*., 2005). Overall, as the complexity of sialorrhoea cannot be overstated, a multidisciplinary management approach ensures an accurate assessment of all contributing factors and leads to appropriate management techniques (Kilpatrick et al., 2000).Therefore, all the related causative factors must be identified, treated or relieved.

Internationally, the multidisciplinary medical team generally includes a primary care physician, a speech and language therapist, an occupational therapist, a dentist, a neurologist (Daniel, 2012; Bavikatte *et al*., 2012), which can be divided into rehabilitation team and the medical team. Each team makes its individualised assessment, analyses factors that contribute to sialorrhoea and identifies strategies to address these factors (Daniel, 2012). It is also proposed that the MDT include social workers, because the medical and physical problems from sialorrhoea can present with complex social and emotional issues, which can be overwhelming and expose a variety of emotional responses (Daniel, 2012). It is therefore essential to make sure that the patient’s social needs are met while managing sialorrhoea. In this instance, the wishes of the individuals and their caregivers are crucial considerations in determining the suitability of the intervention for the patient with favourable responses to interventions demonstrating a reduction in sialorrhoea as well as psychosocial improvements. Consequently, apart from the core healthcare professionals from the pure medical perspective, it is evident that other members of the multidisciplinary team also play important roles in the management of sialorrhoea.

2.6.1 Role of the speech and language therapist

Sialorrhoea can occur as result of a swallowing defect or patient experiencing sialorrhoea might have swallowing difficulties (Erasmus *et a*l., 2012; Binnal *et al*., 2014). Studies establish that amongst patients with PD, swallowing dysfunction is a major component, which might contribute to sialorrhoea (Srivanitchapoom *et al*., 2014). Therefore, in order to provide more control over sialorrhoea, it is suggested that the functional swallowing problems be dealt with in the early stages, subsequently, the aim of speech and language therapy is to increase the awareness of swallowing saliva (Bateson *et al*., 1973; Rashnoo & Daniel, 2014; Srivanitchapoom *et al*., 2014).

The Speech and Language therapists (SALTs) gather information on the patient's medical condition and evaluate its effect on the sialorrhoea management problem (Crysdale *et al*., 2006). The SALTs assess people who have swallowing problems and advise on safe ways for them to eat and drink. Therefore, the SALT plays a crucial role in evaluating the existing oral motor skills of the patient, because often, patients might have difficulty coordinating movements for speech and saliva control simultaneously.

In order to provide more control over sialorrhoea, the SALTs often use a behaviour modification approach (Koheil *et al*., 1987; Nunn, 2000; Van de Burg *et a*l., 2009). A behaviour modification approach adopted by the SALTs involves a combination of cueing, overcorrection and positive and negative reinforcement to help sialorrhoea, swallowing and mouth wiping. It is useful in increasing awareness of the mouth and its function so as to increase the frequency of swallowing (Bavikatte *et al*, 2012). Due to this kind of behavioural therapy, the patient learns to self-control and self-evaluate his/her physical appearance and saliva loss, and learns to prevent or initiate an appropriate response to sialorrhoea (Van der Burg *et al*., 2009). In this way, the therapy can minimise the impact of sialorrhoea control difficulties and improve the patients' wellbeing.

2.6.2 Role of the occupational therapist

The occupational therapists (OTs) also play an important role in sialorrhoea management. Whereby the patient's physical functionality will be assessed from a holistic point of care, including their mobility, posture and head control. This type of assessment is necessary because 'mouth opening' and 'stooped posture' with the head dropping may be causative factors for sialorrhoea (Kalf *et al.,* 2011). OTs may also help the patients to improve their posture with certain devices, it has been established that good posture with the proper trunk and head control provides the basis for improving oral control of sialorrhoea and swallowing (Bivatktte *et al.,* 2012).

It has further been established that stability is essential for optimal oral-motor control, therefore poor head control combined with an open mouth posture can increase the severity of sialorrhoea (Crysdale *et al*, 2006).Consequently, the OTs can help to improve posture and sitting, by incorporating such measures as wheelchair modifications to facilitate better head control. In some cases, other repositioning devices may also be helpful in achieving improved posture. In other words, the OTs manage sialorrhoea by stabilising body and head position, promoting jaw stability and lip closure, whilst also increasing oral sensation to promote swallowing. The OTs can also design a muscle training programme to improve patient's swallowing capacity, such as expiratory muscle strength training (Troche *et al*., 2010). This approach improves cough efficiency (Pitts *et al,* 2009) and it increases submental muscle activity (Wheeler *et al*., 2007), which is vital for hyolaryngeal excursion during swallowing (Kalf, 2013).

2.6.3 Role of the dentist

The role of the dentist in the multidisciplinary team is to carry out an initial assessment of the oral health status of the patient, to co-ordinate any dental treatment required and to monitor the long-term oral health of the patient following sialorrhoea intervention (Kilpatrick, 2000). Dental inflammation may occur due to a lack of oral hygiene caused by sialorrhoea. In addition, wearing dentures and dental pain can cause hyper salivation (Llena-Puy, 2006), at the same time, sialorrhoea can cause significant problems with various phases of denture fabrication and also wearing dentures (Binnal *et al*., 2014). Often people with swallowing problems appear to be at increased risk of poor oral health (Furuta & Yamashita, 2013), and swallowing problems can be associated with sialorrhoea.

In the meantime, depending on the modality used, treatment of sialorrhoea can potentially complicate oral health. In particular the impact of decreased salivation due to the side effects of medication used for treatment of sialorrhoea, as aforementioned, must always be taken into account. Saliva contributes significantly to oral health because it functions as a buffer and a source of ions used for remineralisation of the teeth (Llena-Puy, 2006). Complications due to sialorrhoea such as gingivitis, burning sensation of the mucous membrane, rampant cavities, rapid tooth destruction, cheilitis, commissure fissuring, tongue and palate crusting, and occasionally paresthesia of the tongue or mucous membrane should be addressed (Meningaud *et al*., 2006). Therefore, regular dental examination for tooth decay is recommended for all patients with sialorrhoea (Meningaud *et al*., 2006). Whatever the chosen sialorrhoea management approach, it is mandatory to maintain regular oral examinations with a dentist to prevent or to treat complications related to abnormal salivation.

2.6.4 Role of the nurse/caregiver

Nurses and carers play a pivotal role in providing daily care and support to patients. The nurse and caregiver ‘s caring roles take on countless shapes and forms, with nurses assisting older adults, their friends and family members with small and big tasks on a daily basis. Therefore, caregivers especially nurses sustain the care process and help patients both to cope with complex medical regimes and to manage changes in their daily life while promoting ‘Person-centred care’ and the ‘Patient Health Engagement model’(PHE model) of care. The PHE model and Patient engagement is a developmental process that involves helping the patients’ recover the ability to live their lives to its full potential even if this means living with certain medical conditions (Graffigna & Barello, 2018). In the provision of care to patients with sialorrhoea, generally, the nurse/ caregiver is the one who carries out the assessment of sialorrhoea and who administers any medication required regarding the treatment of sialorrhoea. This condition can pose tremendous challenges for a nurse/ caregiver and can impact on their work performance. Nurses/ caregivers work tirelessly with patients focusing on maintaining the patient’s personal hygiene and dignity in order to decrease the stress caused by sialorrhoea. The support from their nurses/ caregivers to accomplish daily activities improves the patient’s psychosocial well-being (Shelly *et al*., 2008). Nurses/caregivers become crucial in addressing the patients’ needs especially in taking care of older adults who might often display a lack of autonomy in keeping with the principles of person- centred care and the PHE model. In addition to managing the patient’s medical condition and maintaining health, they also provide emotional scaffolding, helping in managing the distressing consequences of illness. Nurse’s clinical knowledge and social knowledge helps to provide patients with the best medical care and social care, supporting the patient’s social role, despite the limitations caused by the disease.

Nurse/ caregiver engagement is a multifaceted and complex process that requires progressive education by the professional care network, favouring the knowledge transfer from the inside to the outside of the hospital setting (Barello *et al*., 2015). Continuing education is crucial for quality improvement in health care (Gaspard &Yang, 2016). However, within the Irish context, there has been very little research carried out into the management of sialorrhoea Therefore the caregiver’s general knowledge of care provision to those patients experiencing sialorrhoea is in urgent need of advancement. This presents the literature gap in relation to identifying the impact of sialorrhoea on patients and on nurses or caregivers. Additionally, there seems to be no recognised training or development programme for best practice for nurses/caregivers.

To conclude, the multidisciplinary approach allows each professional to assess the patient from his/her unique expert perspective which provides a comprehensive and holistic view of sialorrhoea management. It is believed that this approach allows the caring team to provide comprehensive and optimal care to patients. A comprehensive understanding of different sialorrhoea management approaches will enable healthcare professionals to identify the signs and symptoms regarding sialorrhoea, in order to assist effective management implementation. The focus of the multidisciplinary management approach is to ensure that the needs of each patient and their caregivers are considered in determining the appropriateness of the management approach for the patient. This will assist in optimising the management of sialorrhoea to improve quality of life and provide formative scope to develop an integrated care pathway.

2.7 Person-centred care

It is clear that the multidisciplinary management approach for treatment of sialorrhoea is best based on a person-centred care framework. Person-centred care is a recurrent theme within the healthcare literature and is seen as the gold standard when caring for all patients (McCormack & McCance, 2010). Obviously, person-centred care puts the patient at the centre of the care (Love & Kelly, 2011), and the Health Foundation, UK (2017) states that person-centred care is a holistic approach which is to meet the person’s needs, engaging patients in their care as fully as possible and supporting patients to take decisions as much as possible. In this way, person-centred care is seen as the integration of a person’s beliefs, values and preferences in terms of the person’s health whilst designing and implementing healthcare (Hebert, 2010).

The person- centred care approach should be the care standard in all areas of healthcare. Within the Irish context, there are number of standards and acts guiding the care and regulation of older people living in residential care settings including: National Quality Standards for Residential Settings for Older People in Ireland (Health Information and Quality Authority, [HIQA], 2009b); Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) and Regulations 2009. A set of thirty two standards were introduced to ensure patient safety and well-being by covering patients’ rights, protection, health and social care needs along with quality of life of older people (HIQA, 2009b). Subsequently in 2016, HIQA set up 35 mandatory standards to govern the quality of this care including developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.

Person-centred care has been seen to improve patients’ quality of life and abilities to increase self-care (Sidani, 2008; Sjögren *et al.*, 2013), improve patient satisfaction levels (Wolf *et al.*, 2008) and it is the preferred method of care for many patients (Simmons *et al.*, 2014). The focus of healthcare service providers should be on the needs and preferences of service users rather than on what is convenient for the service provider (HIQA, 2012).

Person-centred care encourages coordinated and personalised care, which means that multidisciplinary healthcare professionals will collaborate with each other as well as patients to implement quality provision of care. Patients suffering from sialorrhoea may have different issues or challenges (Crysdale *et al.,* 2005) and the complexity of sialorrhoea requires a person-centred care approach to meet specific needs of individuals. A person-centred care approach should be implemented in the comprehensive assessment of the health status of older people in residential care to make decision on the best management of sialorrhoea.

2.8 Critique of the literature

Literature reviewed followed inclusion and exclusion criteria with a focus on different sialorrhoea management approaches. The quality of original studies regarding sialorrhoea management techniques was assessed using MMAT (Mixed Methods Appraisal Tool; Pluye *et al*., 2011). MMAT contains 19 methodological quality criteria for appraising qualitative, quantitative and mixed methods studies. It allows the assessment of the following five main categories of studies: qualitative studies, randomised controlled trials, non-randomised and descriptive quantitative studies, and mixed methods studies (Pluye *et al*., 2011). There are four criteria for each type of study, to score it, divide the number of criteria met by four (Vrbnjak *et al*., 2016). Studies were excluded from the review with an MMAT score less than 25%, because they were considered to be low (Vrbnjak *et al*., 2016). Furthermore, the majority of the studies are randomised controlled trials (RCT) which is the 'gold standard'. However, some management studies also do not include enough RCT studies, especially in surgical management, therefore case studies and retrospective cohort studies were included in this review.

There is a wide range of studies and review papers carried out regarding sialorrhoea impact and different management approaches with a wide range of assessment tools used in the studies. Studies were carried out worldwide, including countries from

Europe, America and Asia, which provide wider scope of information. However, sample sizes in all the studies are relatively small, ranging from 2 to 93 participants, therefore, the generalisability of findings may be limited due to small sample size. The majority of these studies are quantitative studies and generally, quantitative research methodology requires a large sample size. There were only two participants in studies carried out by Lancioni et al. (2008; 2011) and by de Bruijin et al, (2017), and the method is quantitative observational. Small sample size and observational methods may cause bias and reduce the reliability of the data. Some studies (Stamataki *et al., 2008;* Khan et al., 2016; Kok et al., 2016*)* are retrospective cohort studies. The advantage of this approach is that that it is less expensive to perform and it can be performed immediately because they are retrospective in nature. However, this can lead to poor control over the exposure factor, difficulty in identifying appropriate covariates, and an absence of data on potential confounding factors if the data was recorded in the past (Suchmacher & Geller, 2012). Therefore, the available data may be of poor quality and can also bias retrospective cohort studies.

Quite a few studies are Non-randomised controlled studies (Johnson *et al*., 2004; Van der Burg *et al*., 2009; Dias *et al.,* 2017; Martínez-Poles *et al.,* 2018), which means that assessment of outcome were not blinded and the reported results could lead to inaccurate conclusions. High dropout rate in some studies (Johnson *et al*., 2004; Mato *et al.,* 2009) can also be a threat to internal validity of the data collected. Studies carried out by Stern *et al*. (2002) and Khadivi *et al.* (2013) are case series design, although a well-designed case series study can provide information that allows hypotheses to develop, leading to further advanced studies, it can still be prone to bias, limiting its generalisability to larger populations of patients.

The majority of these studies have a limited scope, either focusing on a single disease category (MND, PD, ALS, or CP) or specific population (paediatric or adult). Various sialorrhoea management approaches have been documented. However, there is no clear consensus on best management practices. Furthermore in the majority of cases, there is no scientific evidence-based management protocol leading to favourable results, and the evidence base for intervention effectiveness remains weak.

The majority of the studies are single method quantitative studies, the results cannot always represent what is actually occurring, and the participants have limited options of responses, based on the selection made by the researcher, which lacks the views of patients or even caregivers. There are also very limited studies evaluating the MDT management approach, although the majority of review papers promote MDT management. Therefore, this study aimed to explore current sialorrhoea management so as to identify best practices protocols from both patients' and healthcare professionals' perspectives.

Overall, the literature included in this review provides comprehensive knowledge regarding sialorrhoea causes, prevalence and management, although there are some limitations.

2.9 Conclusion: Chapter summary

The literature identifies the different approaches involved when managing sialorrhoea, providing understanding and awareness of the different aspects of sialorrhoea, including treatment strategies and the role of MDT members. However, from an analysis of the different management approaches, it seems no one approach provides an ideal management protocol.

As the problem and impacts of sialorrhoea are so significant for so many patients, further high-level quality studies to assess the causes, patient selection, effectiveness and safety of all the mangagement approaches are still required to further improve individual patient outcomes. It is evident from the research to date that a MDT person-centred care approach followed by comprehensive MDT evaluation of the causes for individual patients is essential. However, within the Irish context, it seems there is no clear consensus on best management practices since there is a lack of literature available, and the evidence base for management approach effectiveness remains weak, particularly in the older adult residential settings. Therefore, there is a need to explore sialorrhoea management in the older adult residential care settings within the Irish context from both the patients and healthcare professionals' perspectives.

Chapter 3: Methodology and Methods

Introduction

This chapter outlines the aims and objectives of the research, the conceptual basis and methodological design for conducting an exploration of the care provision of sialorrhoea management and its impact on the patients' quality of life. This study is situated within the methodological approach of a mixed methods design, which encompasses multifaceted procedures that combine and synthesise quantitative and qualitative strategies within the same research project (Driessnack *et al.,* 2007). Section 3.1 outlines the aim and objectives of this research. Section 3.2 explains the theoretical framework. The research philosophy and paradigm underpinning this study and the process regarding the decisions undertaken to select the most appropriate research design are described in Section 3.3. The steps involved in devising a mixed methods design are presented in Section 3.4. Research sampling techniques and sample selection are discussed in Section 3.5. Section 3.6 and 3.7 provide a detailed account of the data collection steps and procedures as well as a description of data analysis methods, whilst section 3.8 presents the ethical considerations for this study.

3.1 Aim and objectives of the research study

The aim and objectives for this study arose from an intention to explore sialorrhoea management options in the older adult residential care settings within the Irish context, and due to gaps identified in the literature review. Therefore**,** the overall aim of this study was to evaluate sialorrhoea management practice within the South East region of Ireland and to subsequently, make recommendations to improve sialorrhoea management.

3.1.1 Objectives:

In order to achieve this aim, the following objectives have been identified:

1. To explore how sialorrhoea impacts on the older adult patients' life.
2. To investigate how sialorrhoea is managed within the South East region of Ireland.

3. To explore the views and challenges in relation to sialorrhoea management practice in care of the older adults.
4. To make recommendations, as appropriate, for the future management of sialorrhoea in the Irish residential care setting.

3.1.2. Research questions

1. How does the presence of sialorrhoea affect older adults' quality of life in residential care settings within the South East region of Ireland?
2. How do older adults with sialorrhoea view the current sialorrhoea management care provision in residential care settings within the South East region of Ireland?
3. What are the management approaches used for the treatment of sialorrhoea among older adults in residential care settings within the South East region of Ireland?
4. How do the MDTs view the current sialorrhoea management care provision in residential care settings within the South East region of Ireland?
5. How do individual caregivers view the issue of sialorrhoea and the implementation of current sialorrhoea management approaches in residential care settings within the South East region of Ireland?

3.2 Theoretical framework

The theoretical framework in research studies serves as a guide and structure on which the researcher can build and support a research study philosophically, epistemologically, methodologically, and analytically (Grant & Osanloo, 2014). It is a foundation upon which research is constructed (Adom *et al.*, 2018). Sinclair (2007) describes the role of the theoretical framework as a map of a travel plan, guiding the journey of research. This study looked at how sialorrhoea was managed in older adults in residential care settings within the Irish context. While no specific theoretical framework for this particular area was identified in the literature review, Person-centred care would seem to provide an appropriate theoretical framework. HIQA, Ireland (2009, 2016) launched a set of standards to ensure patient safety and well-being whilst in the residential care settings through the implementation of a person-centred care approach. Within the person-centred care framework, it refocuses on a crucial aspect of care while fulfilling a patient's needs beyond their disability or ailment. Therefore, a person-centred care approach was a suitable theoretical framework for the study. The main principles of the person-centred care approach outlined by the Health Foundation, UK (2016) were adapted for this study (Figure 3.1).

Figure 3.1. Person-centred care principles adapted from **the Health Foundation, UK (2016)**

Residents, no matter what their specific care needs, should be cared for with the principles outlined in figure 3.1 in mind. Coordinated care means MDT members work together to provide residents with treatment options and choices in order to make sure that resident's different needs are met. Personalised care means care provision is tailored to the needs of individual residents by recognising the residents' concerns and care needs. Enabling and empowering residents, supports people to recognise and develop their own strengths and abilities, to live independently and reach their potential no matter what their medical conditions. Treating residents with dignity, compassion and respect is a fundamental practice of care, each professional has a responsibility to provide care that is respectful and compassionate. Therefore in exploring sialorrhoea management, a viewing with the lens of person-centred approach will ensure that all aspects of the management are considered.

3.3 Research philosophy

While the research methodology displays the approaches to engaging with the research questions (Jamshed, 2014), the research philosophy expresses the researcher's belief about the way in which data concerning a phenomenon should be gathered, analysed and used (Levin, 1988). The research philosophy reflects the researcher's important assumptions and these assumptions serve as a base for the research strategy and design (Bristow & Saunders, 2015). Therefore, the research philosophy fostered in a research study reflects the researcher's basic belief and worldview that guides the research. Research philosophy also demonstrates the ability of a researcher to reflect his or her philosophical choices and defend them in relation to the alternatives that the researcher could have adopted (Saunders *et al*., 2012).

Therefore, the identification of the research philosophy is key to establishing a philosophical orientation as to what paradigmatic base the researcher is going to view their study at the beginning of the research process (Hanson *et al.,* 2005). The research paradigm is a way of looking at phenomena that incorporates a set of philosophical assumptions to guide the author's approach to research inquiry (Polit & Hungler, 2008). It also reflects the methods and techniques utilised for data collection to provide answers to the research questions (Bowling *&* Ebrahim, 2005). In this way, the research paradigm contains three major steps: a researcher makes claims about reality (ontology): how the researcher knows that reality (epistemology) and the process of studying the reality (methodology). Within the various research philosophical paradigms, positivism and interpretivism have been highlighted within the Western tradition of science.

3.3.1 Positivist paradigm

The Positivist paradigm was first proposed by Auguste Comte (1798 – 1857). Positivists claim there is a single, objective reality that can be observed and measured without bias by using standardised instruments (Rubin & Rubin, 2012). Subsequently, positivists believe that reality is stable and can be observed and described from an objective viewpoint (Levin, 1988). Positivist assume that reality exists independently of humans; therefore, researchers fostering the positivist paradigm will take the objectivity of reality which is independent of peoples' perceptions. In this way, positivists believe that reality can be acquired by the use of appropriate research methods and does not change from person to person (Bryman, 2006). In this respect, understanding phenomena in reality must be 'measured and supported by evidence' (Hammersley, 2013, p.22-23).

Hence, positivist researchers detach from the ways in which data are collected and analysed (Creswell & Clark, 2007). In the strict positivist sense, it requires that the researcher stays distanced from what they are studying, as far as possible so that the findings of the research will depend on the nature of the data rather than on the researcher's preferences, personality, beliefs and values (Kivunja & Kuyini, 2017). Therefore, in the positivist paradigm, the researchers see themselves as a neutral recorder, which means different researchers using the same instruments should reach the same conclusions. Research located in the positivist paradigm counts on deductive logic, formulation of hypotheses, testing those hypotheses, offering operational definitions and mathematical equations, calculations, extrapolations and expressions, to derive conclusions (Kivunja & Kuyini, 2017).

In order to address the objective aspect of the study and to reduce any bias, this study looked at how the presence of sialorrhoea impacted on quality of life of older adults experiencing sialorrhoea. Therefore, objective measurement tools were adapted and used to collect data, and these data were analysed using SPSS software. In this way, a positivist paradigm was applied using instruments to explore the objectivity and reality of residents' quality of life, which is independent of the researcher's perceptions.

3.3.2 Interpretivist paradigm

Opposite to the positivist paradigm, the interpretivist paradigm interprets social roles with respect to their own set of meanings and interpretations. The interpretivists propose that reality is centred on each individual's perceptions and experiences (Robson, 2011). Therefore, in the interpretivist paradigm, every effort is made to try to understand the viewpoint of the subject observed, and emphasis is placed on understanding the individuals and their interpretation of the world around them. Using this approach an attempt is made to get into the head of the subjects studied, and to understand and interpret what the subject is thinking. In this way, the key purpose of the Interpretivist paradigm is to understand the subjective world of human experience (Guba & Lincoln, 1989). Interpretivists claim that reality can be utterly understood only via the subjective interpretation and by intervention in reality. Interpretivists believe that researchers cannot distance or detach themselves from reality (Cohen *et al*., 2007). Therefore, the study of phenomena in their natural environments is key to the interpretivism, together with the acknowledgement that researchers cannot avoid affecting those phenomena they study.

3.3.3 Pragmatic paradigm

Pragmatism is a deconstructive paradigm that focuses on ‘what works’ as the truth regarding the research questions under investigation (Tashakkori & Teddlie 2003b, p. 713), and believes mixed methods in research, therefore “sidesteps the contentious issues of truth and reality” (Feilzer 2010, p. 8). Pragmatic paradigm in mixed methods research involves collecting data in a concurrent or sequential manner using methods that originate from both quantitative and qualitative traditions in a manner that best addresses the research questions (Creswell, 2003). Therefore, the pragmatic approach means adopting the research method which best answers the research problem without being confined to philosophical debates about which is the best approach. Creswell (2003) sees pragmatic paradigm has the intuitive appeal, permission to study areas that are of interest, embracing methods that are appropriate and using findings in a positive manner in harmony with the value system held by the researcher. Therefore, pragmatic paradigm solves the debate of the positivist/quantitative and interpretivist/qualitative paradigm and is congruent with real life worldview research.

This study aspired to explore the current sialorrhoea management practice in older adult residential care settings within the Irish context, and therefore endeavoured to identify optimum management approaches under a person-centred care framework. This study evaluated sialorrhoea management practice via three populations, the multidisciplinary healthcare (MDT) members, older adults experiencing sialorrhoea and individual caregivers in regional Irish residential care settings.

In order to explore how sialorrhoea is managed, it is better to understand the experience of the above-mentioned populations. It aims to understand sialorrhoea management approaches through the subjective world of the MDT members, older adults and caregivers (nurses or healthcare assistants). Therefore, the interpretivism paradigm was applied to understand the viewpoints of the study subjects and to interpret their experience and perspectives.

Both of the philosophical paradigms; positivism and interpretivism were applied in this study. Therefore, this study adopted pragmatic mixed methods approach. Mixed methods research is concerned with bringing together numbers and narratives, description and awareness of meaning and context to provide greater understanding of the phenomenon under study (Stange *et al.* 2006). However, mixed methods studies are complex to plan and conduct, since each method must adhere to its own standard of rigour and ensure appropriate quality of each method of the mixed methods study (Wisdom et *al.,* 2011).

3.4 Research design

Research design serves the purpose of providing answers to research questions and controlling variance, and the research design must enable researchers to answer research questions as validly, objectively, accurately and economically as possible (Kerlinger & Lee 2000). Therefore, it was important to select the research design that would best answer the research questions specified above in Section 3.1.2. A research design also describes the procedures for conducting the study, including when, from whom, and under what conditions the data will be analysed.

3.4.1 Mixed Methods Research

Creswell (2003) defines mixed methods research as the collection of qualitative and quantitative data in a single study, involving the analysis and integration of the data at one or more stages in the process of research. Mixed methods research is increasingly being used as a methodological standpoint in health sciences to gain a more complete understanding of issues and hear the voices of participants (Guetterman *et al.* 2015). Mixed methods research involves integrating quantitative and qualitative approaches to generate new knowledge and can involve concurrent or sequential use of these two classes of methods to follow a line of inquiry (Stange *et al.* 2006). The need for mixed methods research in the health sciences is crucial for the exploration of contemporary public health issues (Creswell *et al.* 2011; Mertens 2012). The use of multi-level approaches to investigate complicated health problems and the resident's point of view (Creswell *et al.* 2011) is necessary to improve the quality and scientific power of data in research. Mixed methods research incorporating qualitative and quantitative research is widely used within the domain of social research, and there exists a fundamental distinction between qualitative and quantitative research methods (Table 3.1).

3.4.2 Qualitative research

Qualitative research is empirical research where the data are not in the form of numbers' (Punch, 2003, Robson, 2011), it aims to explore, describe and interpret the individuals' personal and social experiences (Smith & Osborn 2008) via participant observation, interviewing and analysis of documents. Qualitative methods allow researchers to explore the views of similar as well as diverse groups of people to tease out these different perspectives within a community (Choy, 2014), hence this method enables us to understand the social phenomenon. In this way, qualitative research offers a complete description and analysis of a research subject, without limiting the scope of the research and the nature of participant's responses (Collis & Hussey, 2003).

Since qualitative research is subjective data, which makes data collection intensive and time-consuming, often it means small samples are used. In this way, generalisability of the findings to a wider, more diverse population is not an aim of qualitative studies. Therefore, qualitative research methods are often applied in exploratory studies or studies which aim to identify and theorise issues (Corbin & Strauss, 2008; Creswell, 2007). Due to the lack of studies on sialorrhoea management within the Irish context, this study adopted a qualitative research approach to explore participants' perceptions regarding the field of study. These data provide a deep and comprehensive understanding in relation to how sialorrhoea is managed.

3.4.3 Quantitative research

On the other hand, the focus of quantitative research methods is to gather numerical data which aim to generalise them to explain a particular social phenomenon (Muijs, 2010). According to Polit and Beck (2006), the quantitative design is the most appropriate method to apply when the researchers carry out research in a systematic format using formal instruments to collect the required information. Therefore, quantitative research is highly structured to test theories and concepts.

Compared with qualitative research, quantitative techniques produce helpful but limited data which provides a superficial view of the topic under investigation (Creswell & Clark, 2007), due to the fact that quantitative methods seem to force participants to choose from fixed responses rather than give participants freedom to express their own perspectives. Quantitative research mainly focuses on objective measurements and the statistical, mathematical, or numerical analysis of data using computational techniques. These objective data can then be statistically analysed and interpreted so that conclusions can be made on a factual basis (Parahoo,2006). Therefore, in order to find out some factual information regarding how older adults cope with sialorrhoea issues, questionnaires were used to collect quantitative data in this study.

Table 3. 1 Features of Qualitative & Quantitative Research (Adapted from Bryman, 2004, P.94; Minchiello et al., 1990. P.5 and Miles and Huberman, 1994, P.40)

	Qualitative Research	Quantitative Research
Aims	To understand human behaviour from the informant's perspective. Therefore, researcher may only know roughly in advance what they are looking for.	To discover social phenomenal facts. Researcher know clearly what they are looking for.
Data Collection	Data are collected through interviews and observations in the form of words, pictures, videos or objects, and are analysed by themes emerging from descriptions by informants. Data are reported in the language of informants.	Data are collected through measuring instruments such as questionnaires, and are analysed through numerical comparisons and statistical inference. Data are reported through statistical analysis.
Relationships between researcher and research subjects	Close	Distant

Scope of findings	Emergent, qualitative data are time consuming and less able to be generalised.	Nomothetic, quantitative data are more efficient, and are able to test hypotheses, but may miss contextual details.
Role of researcher	Researcher is the data gathering instrument, and may tend to become subjectively immersed in the subject matter.	Researcher uses tools to collect data and tend to remain objectively separated from the subject matter.
Research strategy	Unstructured	Structured
Nature of data	Rich, deep	Hard, measurable

3.4.4. Justification for the selection of Mixed Methods design

Since each single research method has its strength and weakness, using mixed methods not only takes advantage of the strength of both methods, but also compensates for the limitation and weakness of a single method (Hammond, 2005). In the quantitative approach, the researcher employs predetermined and fixed strategies such as experiments and surveys that help to collect statistical data. The qualitative approach includes flexible strategies based on open-ended questions and observational data. In this way, mixed research methods in a study can provide a more holistic picture of a phenomenon by approaching it in different ways. Therefore, the mixed methods approach can potentially capitalise on the respective strengths of qualitative and quantitative approaches (Ostlund *et al.*, 2011), and can also provide stronger concluding evidence through convergence and validation of the research findings (Johnson & Onwuegbuzie, 2004).

The structure of the process regarding the choice of mixed method design is illustrated in ‘The Decision Tree’ (Figure 3.2). The decision tree provided the structure with regard to getting ‘the right fit’ with regard to the choice of mixed method design. With respect to this research study, it was deemed that this study is better situated within the methodological approach of a mixed methods framework, integrating quantitative and qualitative tools to foster a greater understanding of the experiences of older adults living with sialorrhoea.

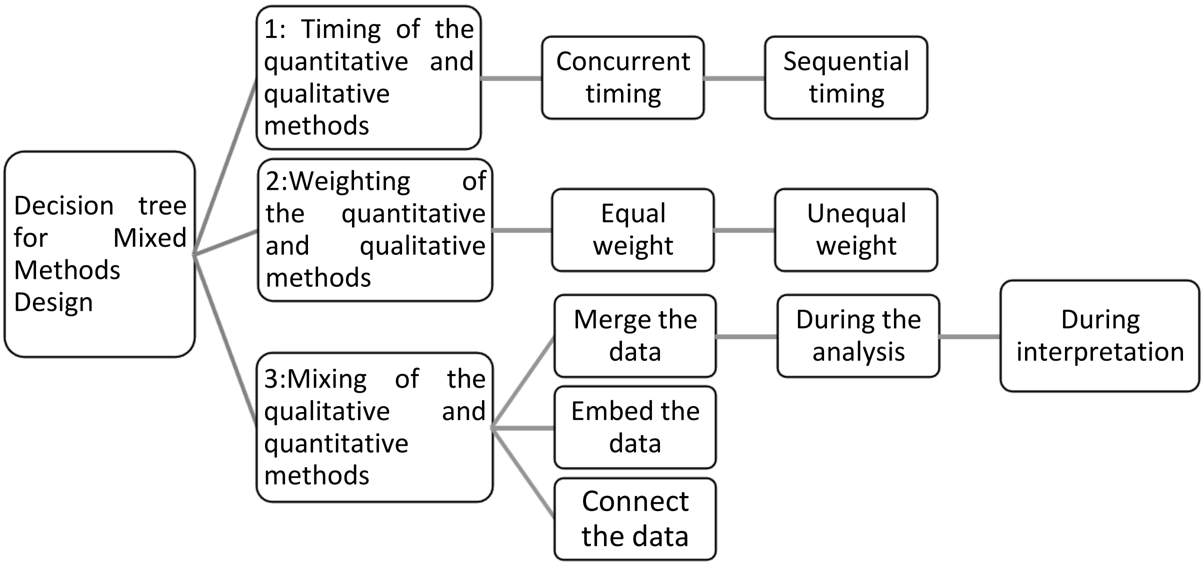


***Figure 3.2. Decision tree regarding mixed methods design (Creswell et al., 2003; Creswell & Clark, 2007*).**

A mixed methods design provided a more complete and comprehensive picture of the study phenomenon (Bryman, 2008). The mixed methods approach is in response to the limitations of single research methods and is now considered by many as a legitimate alternative to single quantitative or qualitative methods (Doyle *et al.,* 2009). It is also suggested that mixed methods investigations may be used to gain better understanding of research problems by converging numeric trends from quantitative data and specific details from qualitative data (Tashakkori &Teddlie, 2010b; Mertens, 2012). Therefore, using a mixed methods approach has the advantage of providing insight when explanation of the findings are required (Andrew & Halcomb, 2009). Using a mixed methods approach, the research aims to build on the knowledge on pragmatic grounds (Creswell, 2003). Pragmatists accept the problem solving function of human beliefs. All human activity arises from the need to solve problems (Andrews & Halcomb 2009). Pragmatists further choose approaches which are most appropriate for finding an answer to the research question (Tashakkori & Teddlie, 2010). A major view of pragmatism is that quantitative and qualitative methods are compatible and therefore quantitative and qualitative data collected concurrently or sequentially can enhance comprehension of the research problem (Andrews & Halcomb 2009).

For the purpose of this research, it is believed that a mixed methods research approach incorporating qualitative and quantitative approaches is suitable to address the issue of sialorrhoea among older adults in the residential settings. Hence, the methods applied in this study complement each other, allowing a deeper description and a broader insight into the cases than would have been discernible solely from one method. This mixed method study design included concurrent phase 1 and sequential explanatory phase 2. Concurrent phase 1 was chosen to explore views of both older adults and MDT in order to get deeper and fuller understanding of sialorrhoea management practices in older adults residential care settings. A sequential explanatory design was chosen for phase 2 where phase 1 results were used to assist in explaining and interpreting the findings of phase 1. Findings from the survey with older adults, where the impact of living with sialorrhoea and its current management were investigated, together with the opinions of the MDT lead to the development of the topic guide for phase two interviews. Phase 2 interviews investigated further the impact and management of sialorrhoea on the study population by interviewing those caring for the population of interest on a daily basis.

During the literature review stage of this study, it seemed that there was a dearth of knowledge regarding sialorrhoea management within the Irish context. Therefore, interview methods were used to explore and identify emerging themes regarding the study area and data collection methods included in-depth interviews using open-ended questions with the multidisciplinary healthcare teams and residents' caregivers (nurses or healthcare assistants). In the meantime, in order to investigate residents' medical conditions and how sialorrhoea impacts on residents' quality of life, more statistical and structured factual information was needed. To meet the objectives of this study, a mixed methods approach was adopted, which accommodated further exploration of the survey data by the use of focus groups interviews as well as one to one interviews. Therefore, the breadth and scope of this study have the potential of incurring significant advances in the clinical area, as directly informed by the findings of this research study.

3.4.5. Research design for this study

The research design is illustrated in Figure 3.3

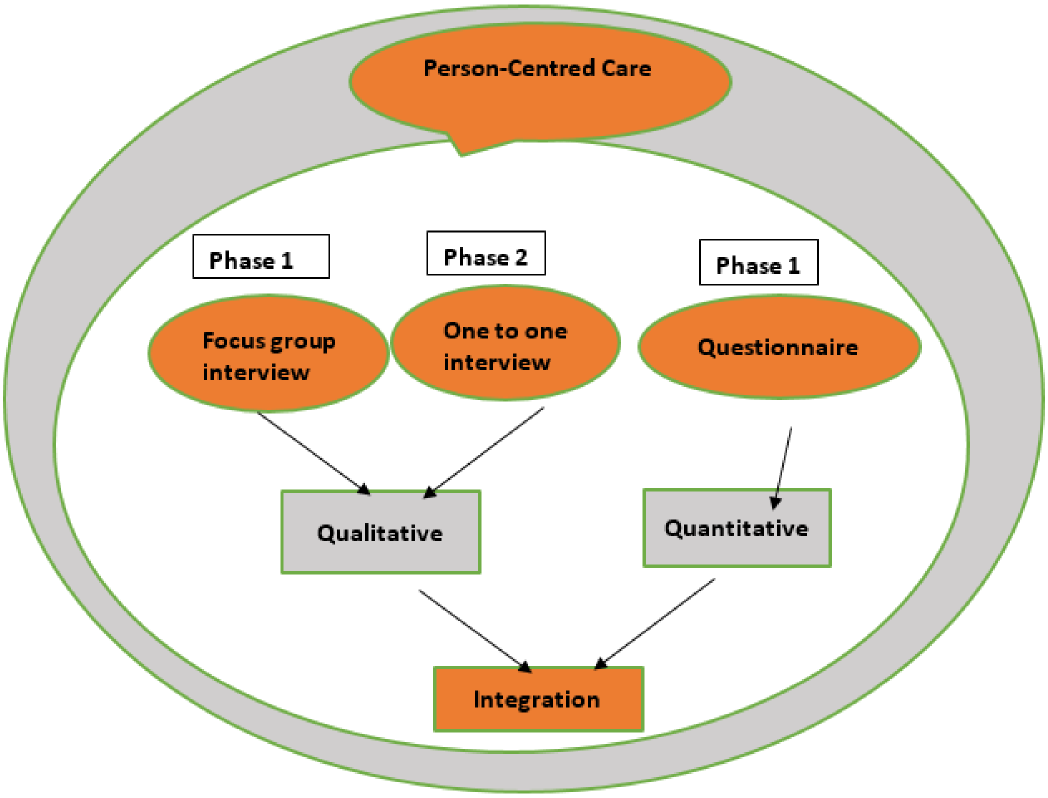


Figure 3.3. Research design for this study

The design of this study adopted a mixed methods approach involving two phases combined to answer the overall central aim. The two phases in this study were designed to answer the overall question 'how is sialorrhoea managed?' by mixing quantitative and qualitative data across levels of analysis and integration (Schoonenboom & Johnson, 2017). Questionnaires and interviews as classic social sciences research tools (Greenfield, 2002; Silverman, 2004; Sarantakos, 2013) were utilised in this research study design. Therefore, the mixed methods utilised in this study included a quantitative cross sectional, descriptive correlational survey and an exploratory descriptive qualitative design. These incorporated perspectives from the multidisciplinary team, residents and caregivers, which allowed the evaluation of sialorrhoea management practice in older adult residential care settings within the Irish context.

3.4.6 Research process

This research design process can be visualised in table 3.2 below which displays the processes, procedures and outputs involved with mixed methods studies. The first phase was concurrent in design and involved the multidisciplinary healthcare team focus group interviews and the older adult questionnaires. Due to the European General Data Protection Regulation (GDPR; 2016) which came into effect in May 2018 and their impact on recruitment, a second phase (an emergent phase) was added which was sequential in design. It involved one to one caregiver (nurses or healthcare assistants) in-depth interviews. This phase was deemed necessary to further explore the findings emerging from phase 1. While the researcher would have liked to interview older adults in the residential setting, this was not possible as in order to fully comply with GDPR decision-making and the consent process, residents need to be fully informed about the study and then make a decision whether they consent to participate or not. However, the older adults who would be participating in the interview had neurological conditions that may have compromised their mental capacity. Therefore there was limited access to the resident group because of consent issues related to perceived capacity. This was due to the fact that family members could no longer give consent for their relatives in care, as according to the new GDPR regulations, consent to participate can only be received directly by the resident or a legal representative. Therefore, an additional qualitative phase focused on caregivers' perspective became necessary in order to answer the research questions and develop a further understanding of the results from the previous phase. Data from both phases were then interpreted and integrated to evaluate the current sialorrhoea management practice.

Table 3.2 Overview of research process

Aim	**Phase 1 (Strand 1)**	**Phase 1 (Strand 2)**	**Phase 2**
	To identify the severity and frequency of sialorrhoea and aspects of quality of life that were impacted by sialorrhoea and their views on the provision of sialorrhoea management practice.	To explore the views of the multidisciplinary (MDT) healthcare team caring for older adults with sialorrhoea regarding aspects of quality of life that were impacted by sialorrhoea and sialorrhoea management practice.	To explore the views of caregivers (nurses or healthcare assistants) caring for older adults with sialorrhoea on daily basis regarding sialorrhoea management practice and the impact of sialorrhoea on quality of life.

Study population	Older adults with sialorrhoea in residential care settings	The multidisciplinary healthcare team members in care of older adults in residential care settings.	One to one caregivers (nurses or healthcare assistants) in care of older adults with sialorrhoea in residential care settings.
Data collection	Questionnaire	Semi-structured focus group interviews with MDT healthcare members	Semi-structured interviews with caregivers (nurses or healthcare assistants)
Main outcome	Sialorrhoea severity and frequency scales, aspects of quality of life affected by sialorrhoea. Experience of older adults with sialorrhoea management provision	Illuminate and describe the experiences of the MDT healthcare members while caring for older adults with sialorrhoea in order to evaluate sialorrhoea management practice	Illuminate and describe the experiences of caregivers caring for older adults with sialorrhoea. Describe the impact of sialorrhoea on the older adult's quality of life to further understand findings from phase1.
Analysis	Descriptive statistics and thematic analysis.	Thematic analysis	Thematic analysis

3.5. Target population & sample

A target population in research is a complete set of people with a specific set of characteristics, and a sample is a subset of the population (Banerjee & Chaudhury, 2010). In order to answer research questions, it is considered to be standard practice to establish inclusion and exclusion criteria for the study population (Patino *et al.*, 2018). There were three populations of interest for this study. The first population were the older adults experiencing sialorrhoea (and their carers where required) in the South East region residential settings. Second population were members of the MDT sialorrhoea management team in the South East of Ireland residential care settings, including nurse directors, nurses, care assistants, speech and language therapists, occupational therapists, physiotherapists, dentists, and GPs/ neurologists. The third population were the caregivers (care assistants or nurses) who were closely looking after residents with sialorrhoea issues, and those that participated in the MDT interviews were excluded. A sample size was determined for each population in the following sections (Section 3.5.1; 3.5.2 and 3.5.3).

3.5. 1 Questionnaire Sample Size calculation

Generally, the target sample size for a survey depends on the following factors: the resources available, the aim of the study, and the statistical quality needed for the survey (Kelley *et al.*, 2003). It is standard practice to use computer packages to conduct sample size calculations for statistical data analysis. In order to work out the sample size for the older adults participants, the following calculation was carried out. The most recent census in Ireland reported that the number of usual residents aged 65 years and older enumerated in nursing homes actually rose to 22,762 persons in 2016. (Central Statistics Office; CSO, 2016). Furthermore, a report carried out by Sheery FitzGerald (2015) on the Nursing Home Market reported that 3,236 long-term beds were available in the South East region. Based on these figures and the fact that the literature states on average 50% of the population with neurological disorders will suffer from sialorrhoea, the sample size calculation was based on a population of 1,618 within the South East region.

This sample size was determined using an online survey sample size calculator (Creative Research Systems, 2012) which is available as a public service of Creative Research Systems survey software. The quantitative strand of the research question was addressed using a sampling frame with a 95% confidence level (as used by most researcher; Conroy 2012). The 'Sample Size Calculator' was used to determine how many people were required to survey in order to achieve results that reflected the target population for the study. The calculation was based on the number of residents residing in a nursing home in the South East of Ireland suffering from sialorrhoea as calculated above (n=1618). Using a confidence level of 95%, and a confidence interval of 10, the recommended sample size was 95 participants.

3.5.2. Focus group interview sample size

In relation to focus group interviews recommended number of participants, it is suggested that it should range from 6 to 12 participants by many authors (Morgan, 1997; Patton, 2002; Ritchie & Lewis, 2003; Denscombe, 2007). Similarly, Kitzinger (1995) suggested that the ideal size of a focus group is 4 to 8 participants. The reason behind this is with a low number of participants, the information gathered may not be rich and adequate and one or two persons may attempt to control the conversation. On the other hand, a group with big numbers of participants is practically difficult to manage, and the group may break into factions and participants may not find adequate opportunities to talk in a big group. In this study, focus group interviews were carried out until the point of data saturation was reached. A recent publication by Guest *et al*. (2016) stated that more than 80% of all themes were discoverable within two to three focus groups, and 90% were discoverable within three to six focus groups and hence three focus groups were recommended as sufficient to identify all of the most prevalent themes within the data set (Guest et al, 2016). However in this study, it was agreed to collect data from focus groups until the point of saturation had been reached and no new themes were emerging (Taylor 2012).

3.5.3. One to one interview sample size

Qualitative research generally uses a small sample size to facilitate deep exploration and the generation of data that has depth of understanding (Ritchie *et al.* 2003). Well-conducted interviews with a small sample size of communicative and well informed participants obtain high quality data, therefore the point of data saturation will be reached quickly and the small sample size will be sufficient (Burns & Grove 2003). For the purpose of this study, the additional qualitative phase with caregivers, one to one in-depth interviews were carried out until data reached saturation.

3.5.4 Sampling method

This research adopted a multilevel sampling method, which involved the use of two or more sets of samples that were extracted from different levels of the study or from different study populations (Onwuegbuzie & Collins, 2007). Kemper et al. (2003, p. 287) defined multilevel sampling in a mixed method study as occurring when ‘probability or purposive sampling techniques are used on different levels of a study’. Using different populations within a study reflects various levels of the research area. Within this study, both the older adult and healthcare staff populations in older adult’s residential care settings were chosen.

Purposive sampling is a form of non-probability sampling, where people from a pre-specified group are purposely sought out and sampled (Procter & Allan, 2007). Purposive sampling allows the researcher to identify participants who will provide the necessary data to answer research questions (Miles & Huberman, 1994). Therefore, purposive sampling increases the collection of data that is information rich and also increases the likelihood of getting the opinions of the target population (Parahoo, 2006). In this study, multilevel sampling offered the advantages of choosing samples from the older adults with sialorrhoea issues and various care provider groups in the direct provision of sialorrhoea management to provide perspectives of different groups.

3.5.5 Inclusion and exclusion criteria

In order to assist the researcher to answer the research question, Bryman (2008) suggests that inclusion and exclusion criteria must exist in order to achieve accuracy of the study and data collected. The inclusion and exclusion criteria of the different populations within this study are described below.

Inclusion criteria for members of MDT

- Members of MDT were aged 18 years or over.
- Members of MDT were involved in some way with the care of persons experiencing sialorrhoea.
- Members of MDT had sufficient English language skills. For the purpose of the study's ethics proposal, sufficient English language skills referred to the participants' ability to properly and adequately receive, interpret and converse feedback to the interview questions using the English language without any major language insufficiency.
- Members of MDT were currently working with the older adults in the provision of care.
- Members of MDT were qualified within their chosen profession with at least 6 months post–registration experience.

Exclusion Criteria for members of MDT

- Members of MDT who were not involved in some way with the care of sialorrhoea
- Members of MDT who didn't have sufficient English skills.
- Members of MDT who were not currently working with older adults in the delivery of care.

Inclusion criteria for older adults

- The older adults were aged 60 years or over.
- The older adults were currently residing in residential care services.
- Where capacity to give informed consent was lacking, consent was sought from their legal representative if they had any, otherwise, these older adults were excluded from this study due to legal binding of informed consent.
- The older adults had the presence of sialorrhoea, regardless of severity and frequency of sialorrhoea.
- The older adults had sufficient English as highlighted above.

Exclusion criteria for older adults

- Older adults who had insufficient English skills.
- Older adults who lacked capacity to give informed consent and had no legal representatives.
- Older adults who had an absence of sialorrhoea.

Inclusion criteria for caregivers:

- Caregivers were aged 18 years or over.
- Caregivers had sufficient English language skills.
- Caregivers were actively involved with the care of residents experiencing sialorrhoea.
- Caregivers were currently working with the older adults in the provision of care.
- Caregivers were qualified within their chosen profession with at least 6 months post registration experience.

Exclusion Criteria for caregivers

- Caregivers who were not involved in some way with the care of residents experiencing sialorrhoea.
- Caregivers who were not currently working with older adults in the delivery of care.
- Caregivers who had attended the MDT interview in phase 2.

3 5.6. Sample access and recruitment

This section gives an account of the procedures involved with recruiting the target population to participate with the study. It includes how access was granted to the sample setting and how participants were invited to take part within the study.

This project was funded under the Nursing and Midwifery Planning and Development Unit (NMPDU), Health Service Executive (HSE) South East Ireland. This region includes HSE state owned and private residential settings for older adults. Contact information of the community hospitals and private nursing homes was gathered by initially deskwork searching.

The next stage of this study was to gain access to the older adult residential care settings. Gaining access to the research sample was a crucial component of the research process and required the researcher to negotiate and plan with all the relevant stakeholders (Woods & Roberts, 2003). Following receipt of ethical approval (Appendices B,C, D, E) from the appropriate authorities and in order to safeguard all participants within the study, the Directors of Nursing at the chosen older adult residential care settings were forwarded a letter (Appendix L) requesting access and permission to conduct the research within the facility.

Subsequently, meetings were set up with the Directors of Nursing who granted access to sites to allow open communication between the necessary parties. Information leaflets and a plan of how the study would be conducted were presented to the gatekeepers and all concerns and queries were addressed. By opening the lines of communication, a good rapport was established with the gatekeepers who proved to be valuable to the researcher. The Directors of Nursing appeared to be in approval of the research study being conducted within the care setting, provided it met the ethical approval of the relevant authorities.

All older adults, multidisciplinary healthcare professionals within older adult residential care settings were given the opportunity to participate in the study. Information sessions were carried out at each site. After each session, information leaflets were distributed to all potential participants to ensure all were informed. All information leaflets (Appendices F&G) contained a contact number for the researcher should any question have arisen. An email was sent to the Directors of Nursing, with follow-up achieved by phone calls. This procedure was repeated to recruit one to one participants for the added phase 2 study (Appendices N&O). The sites were visited multiple times over one year.

3.6 Data collection methods and Data collection

The timeframe for data collection procedures was twelve months, from October 2018 to October 2019. This research study applied both qualitative and quantitative methods to explore sialorrhoea management. Methods of in-depth, semi-structured, open-ended interviews within focus groups and also on a one to one basis were applied. In addition, questionnaire survey analysis was also employed. The various stages of the study were organised as follows: i) scoping visit; ii) main fieldwork period; iii) primary analyses; iv) third field visit; v) analyses of focus group interviews with the help of NVivo text analysis programme; Vi) Quantitative data analysis with help of SPSS; Vii) Analyses of one to one interviews with the help of NVivo text analysis programme; Viii) findings and data interpretation and integration.

Questionnaire data collection was carried out over nine months, January- September 2019 and involved eleven older adult residential care services. Older adults with sialorrhoea issues who met the inclusion criteria were given oral and written information about the study. The management of the residential care settings and the researcher decided who met the criteria, on the day of questionnaire data collection, the researcher was always accompanied by a healthcare member (nurse or Direction of Nursing). Residents were again given information regarding the survey so as to check understanding for decision making and verbal consent was required before filling in the questionnaire. Both the researcher and healthcare member were present at the time of survey in case any help was needed and if any questions arose. The survey was carried out in the morning after their tea break and before lunch because management of the residential care decided that was the best time for the residents. The survey was also carried out in resident’s room unless it was requested by the residents to complete the survey in a public area. It normally required approximately 15-20 minutes for residents to complete questionnaires, then questionnaires were returned to the researcher.

Focus group interviews occurred in five residential care settings in their staff meeting areas. Prior to the commencement of the focus group interview any questions were addressed. The principles of confidentiality and anonymity were re-enforced. All participants were advised the interview was recorded and they could stop the interview at any time. One or two mediators were present to avoid any bias and helped to take notes. The length of time for each interview varied between 22–36 minutes.

One to one interview occurred in five residential care settings. Directors of Nursing were contacted first with information and details of the study. The Director of Nursing then contacted individual nurses or healthcare assistants seeking any interest in participating in the study. The researchers made contact once permission was given from the nurses or healthcare assistants in order to provide more information about the study and arrange the interviews. Interviews were carried out in staff meeting rooms, prior to the commencement of the interview any questions were addressed. The principles of confidentiality and anonymity were re-enforced. All participants were advised the interview was recorded and they could stop the interview at any time. The length of time for each interview varied between 13–21 minutes.

3.6.1 Pilot study

A pilot study is a preliminary trial of the research study that is designed to test the suitability of the instruments to be used, to identify potential and actual problems with data collection and to examine analytical strategies (Patton, 2002; Polit & Beck, 2008). Therefore, a pilot study was carried out to ensure the viability of the planned research approach.

Prior to carrying out the pilot study, an expert panel was consulted, regarding the questionnaire and the semi-structured topic guides, who provided critical feedback. The questionnaire pilot study was carried out with 3 participants to check for ambiguities in relation to the understanding of questions and enquire regarding the length of time for completion of the survey. In relation to the semi-structured topic guides, as there was no previous study of this nature in Ireland, three members of the MDT participated the interview using the topics in order to assess the acceptability of the topic guides and to check for ambiguities in relation to the understanding of the topics. The one to one interview topic guide was reviewed by three caregivers to check the suitability of the topics.

Pilot study participants' feedback was recorded and amendments made accordingly. The pilot group participants were excluded from the subsequent main study. The final interview topics and questionnaire were agreed between the researcher and the supervisors and the survey commenced following incorporation of the minor amendments suggested by the pilot study results.

3.6.2 Data collection method 1: Older adult questionnaires

Questionnaires usually focus on people, their beliefs, opinions, attitudes, motivations and behaviour (Kerlinger & Lee, 2000). Questionnaires generally provide a relatively simple and straightforward approach to the study of attitudes, values, beliefs and motives (Robson, 2002). Questionnaires are a structured approach to data collection and analysis, which are suitable for providing factual, descriptive information. In order to improve cost-effectiveness, reliability and validity, it is advisable to use validated instruments that are well designed and easy to use (Parahoo, 2014). The questionnaire (Appendix K) used in this study contained 4 sections. The first section contained demographic information of the participants, including gender, age, main diagnosis, mobility, speech and sialorrhoea management approach. The second section was a previously developed tool, the 'Drooling Severity and Frequency Scale' (DSFS; Thomas-Stonell & Greenburg, 1988). The third section again contained a previously developed tool, the 'Clinical Saliva Scale for Motor Neuron Disease' (CSS-MND; McGeachan *et al.*, 2015) with extra items added. These extra items were identified following findings from literature review. The last section was six open-ended questions to explore the views of participants in relation to sialorrhoea management and recommendations.

The data collection process involved administering questionnaires (Appendix K) to older adults experiencing sialorrhoea. Two scales were included in the questionnaire, the DSFS (Thomas- Stonell & Greenburg, 1988) and the CSS-MND (McGeachan *et al*., 2015). Thomas- Stonell & Greenburg (1988) introduced the DSFS for subjective assessment of severity and frequency of sialorrhoea. The DSFS included the scores from two items. 'Drooling Severity' was given a score ranging from one to five, and the 'Drooling Frequency' was scored between one and four. Participants were asked to rate the severity and frequency of sialorrhoea, and the DSFS total score was the combination of the two scales ranking from 2-9. This ordinal scale was adapted and used in many other studies (Santamato *et al.,* 2008; Mato *et al.*, 2010; Parr *et al*., 2014; Assouline *et al.,* 2014).

However, the DSFS did not address impact on quality of life which residents might experience. Therefore, the CSS-MND was added to the questionnaire to measure the impact of sialorrhoea on residents' quality of life. The CSS-MND is an add-on from the Sialorrhoea Clinical Scale for PD (SCS-PD; Lloret *et al*., 2007).The CSS-MND is a subjective perception of discomfort related to sialorrhoea. These scales are resident-reported measures for the impact of sialorrhoea containing nine items, severity of impact of each item is divided into 4 degrees with 0 indicting no impact, 3 indicating severe impact (McGeachan *et al*., 2015). The SCS-PD scores range from 0 (minimum) to 21 (maximum) intensity (Lloret *et al*., 2007), the CSS-MND scores range from 0 to 27. Following consultation with academic supervisors, these scales were divided into three categories by dividing the total scores with 3, with each category indicating low impact, medium impact and high impact. The CSS-MND was used to reflect: 1.impairment resulting from sialorrhoea when eating or speaking, and social restrictions; 2. the presence, severity, and timing of sialorrhoea; 3. the relationship between meal times and sialorrhoea; 4. The impact of coughing as a result of excessive saliva spilling into the resident's throat and the impact of excessive saliva on the use of non-invasive ventilation (NIV). Of note, the impact of excessive saliva on the use of NIV was deleted from the questionnaire due to lack of access to certain participants. Following the literature review, pilot study and consultation with academic supervisors, three extra items were added to the tool to assess 1. The existence of skin rash due to sialorrhoea 2. Mouth wiping frequency due to sialorrhoea. 3. Social avoidance due to sialorrhoea. This scale is called the 'Revised Sialorrhoea Impact Scale'.

The DSFS was adopted in this study to measure the frequency and severity of sialorrhoea as it has been widely used across different age groups (Santamato *et al.,* 2008; Mato *et al.*, 2010; Parr *et al*., 2014; Assouline *et al.,* 2014). The SCS-PD was used in older adults with PD (Lloret *et al*., 2007) and the CSS-MND was used in studies with older adults with MND (McGeachan *et al*., 2015). Therefore, the CSS-MND was adopted in this study due to the similar participants' age group and medical conditions. The decision to choose the DSFS and the CSS-MND scale was based on the concise clear nature of the tools and their ability to measure key factors that evaluated severity and frequency of sialorrhoea and how sialorrhoea impacted on the quality of life among older adults experiencing sialorrhoea.

3.6.3 Data collection method 2: Semi-Structured Focus group interview

Focus group interviews with a semi- structured topic guide (Appendix J) were utilised in this study. The rationale involved was that a semi-structured group session encouraged participants to think together, inspire and even challenge each other to react to the emerging issues and points (Dörnyei, 2007). The dynamics and social interaction in the discussion between group members was essential (Halcomb *et al.,* 2007) to generate a richer and more complete understanding of the issues investigated (Asbury, 1995; Krueger, 1996; Krueger & Casey, 2000).

Semi-structured focus group interviews were utilised in this study to meet the aims and objectives of the study but also to allow opportunities for the participant to talk openly and freely (Streubert & Carpenter, 2011). There were four sections in the topic guide (Appendix J) including 17 questions, and the questions were developed from the key themes from the literature review. These questions sought to find out general information regarding sialorrhoea prevalence, causes and impacts on residents, sialorrhoea assessment tools, management approach, views and evaluation including challenges and recommendations of current management practice. These focus group interviews were utilised to explore the views of the MDT which provided a second lens through which to explore the current sialorrhoea management and enabled further depth and understanding of the issue.

3.6.4 Data collection method 3: One to one interview

Compared with questionnaires, interviews are more powerful in eliciting narrative data, which allows researchers to investigate people's views in greater depth (Kvale, 1996; 2003; 2006). The semi-structured interview guide is a schematic presentation of questions or topics and need to be explored by the interviewer (DiCicco-Bloom & Crabtree, 2006), which provides more systematic and more depth of understanding of the social phenomenon (see Appendix M for topic guide). Semi-structured interviews provided structure to meet the aims and objectives of this study but also allowed opportunities for the participant to talk openly and freely (Streubert & Carpenter 2011). In this study, the one to one interviews were utilised to develop further understanding of the findings from phase 1 of the study.

One to one interviews were added as an additional phase due to the small number of questionnaires collected in Phase1, Strand 1. The one to one interview topic guide (Appendix M) was developed based on the findings from the phase 1 questionnaires and focus group interviews. The topic guide included three main sections containing 11 questions in order to develop further understanding of findings from Phase 1 of the study.

3.7 Data analysis

Polit and Beck (2006) defined data analysis as the systematic organisation of research data in order to address a research question. The intention of the following section was to provide a step-by-step approach to the data analysis processes.

3.7.1 Quantitative data analysis

Quantitative data analysis was performed using the Statistical Package for the Social Sciences (SPSS) Version 25. Data generated from the questionnaires was entered into the database systematically and was double-checked during the entering process to prevent any errors. Firstly, frequency tests and case summaries tests were run in SPSS

25 to check for errors and then a missing data test was run in order to decide whether to remove any data due to missed questions during data collection.

The initial analysis of the resident questionnaire surveys reviewed the demographic details of the participants of the study. These variables included age, main diagnosis and mobility, treatment types were assigned a numerical value. The values of the DSFS scores, the CSS-MND scores and added items regarding sialorrhoea management approach and life satisfaction were also entered into SPSS 25. Means and standard deviations (SD) were used to present continuous variables, with categorical data being presented in number form and percentages.

Normality tests were run, and data was summarised using non-parametric statistics such as *Spearman's* correlations, where appropriate, to examine the relationship between continuous variables. *Kruskal-Wallis* tests *and Mann Whitney U* tests were used, where appropriate, for comparisons between groups of management approach and life satisfaction.

3.7.1.1 Establishing rigour in quantitative phase

Quantitative research follows a structured, rigid, preset design with the methods all prescribed. Rigour in quantitative research refers to the thoroughness and precision of a study in terms of empirical validity, statistical significance, and the generalisability of results (Flickinger *et al.* 2014). This section explains how validity for quantitative research was achieved in terms of validity, reliability, and generalisability.

3.7. 1.2 Validity and reliability of questionnaire tool

In quantitative research, validity and reliability of the instrument are important for decreasing errors that might arise from measurement problems in the research study. The appropriateness of measurement instruments and the extent to which reliability and validity are demonstrated have a profound influence on the findings and the internal and external validity of a study (LoBiondo-Wood & Haber, 2010). Validity refers to whether a measurement instrument accurately measures what it is supposed to measure (Polit & Hungler, 2008), while reliability means that the measurement is consistent and accurate (Polit & Beck 2008; Polit & Hungler, 2008). Content validity refers to the data collection instrument and that the data collected meets the research aims and objectives (Playle, 2000). The questionnaire underwent scrutiny of the content and the full range of factors under study to fulfill the research aim. Content validity pertaining to the questionnaire items was sought from the panel of experts which consisted of three nurses in a clinical setting, a statistician and two academic research personnel involved in previous research. The experts reviewed the questionnaire in order to assess whether the questions were relevant to the subject it aimed to measure. In this study, the results of the pilot survey helped to establish stability and internal consistency, reliability, face and content validity of the questionnaire.

Face validity, which is a subtype of content validity, is a rudimentary type of validity, refers to whether the instrument appears valid, and looks as though it is measuring the appropriate construct (Polit & Hungler, 2008). Face validity in this study was established through expert opinion through an examination of the questionnaire that identified the variables involved within the research topic.

The reliability of an instrument is the degree of consistency that it measures (Polit & Beck, 2008). The reliability of an instrument can also be defined in terms of accuracy, consistency and the predictability of specific research findings. If the results of a study can be reproduced under a similar methodology, then the research instrument is considered reliable (Joppe, 2000). The most widely accepted statistical measurement of internal consistency and reliability is Cronbach's (1951) Alpha co-efficient. Cronbach's Alpha measured the internal consistency of the items in the questionnaire and demonstrated good internal consistency. All questionnaires had subscales that were also examined using Cronbach's alpha coefficient. A value above 0.7 is regarded as being optimal for internal consistency (Bryman, 2008; LoBiondo-Wood & Haber, 2010). However, due to the small sample size in the study, the higher value of 0.8 Cronbach's alpha score while being regarded as optimal for internal consistency (Bujian et al., 2018) may lead to a potential type 1 error. The small sample size would be associated with large standard errors, however the revised survey is based on validated questionnaires which have demonstrated good internal consistency as demonstrated in the studies reported in Table 3.3. As explained in section 2.6, although the DSFS was not tested for reliability, it has been widely used in many studies (Santamato *et al.,* 2008; Mato *et al*., 2010; Parr *et al.,* 2014; Assouline *et al*., 2014) and considered to be effective. As to the SCS-PD and the CSS-MND, Table 3.3 shows the Cronbach's alpha coefficient with different subscales conducted in previous studies by Llret *et al.* (2007), and McGeachan *et al.* (2015) using the research tool. Results from the current study are also displayed in table 3.3.

Table: 3.3 Questionnaire adapted reliability tests.

	Type of study	**Cronbach ' s alpha**
Previous studies	Full CSS-MND scale (n=17), McGeachan *et al.* (2015)	0.624
	Abbreviated CSS-MND 1 excluding the items relating to both speech and NIV (n=50), McGeachan *et al*. (2015)	0.539
	Abbreviated CSS-MND 2 excluding the item relating to speech (n=21), McGeachan *et al*. (2015)	0.649
	Abbreviated CSS-MND 3 excluding the item relating to the use of NIV (n=42), McGeachan *et al*. (2015)	0.554
	SCS-PD (n=42), McGeachan *et al*. (2015)	0.681
	SCS-PD (n=37), Llret *et al*. (2007)	0.78
Current study	Abbreviated CSS-MND excluding the item relating to NIV (n=35)	0.857
	SCS-PD (n=35)	0.856
	Revised Sialorrhoea Impact Scale (n=35)	0.89

A reported Cronbach's alpha coefficient of 0.89 of the 'Revised Sialorrhoea Impact Scale' used in the current study validated that the use of the questionnaire with adults with sialorrhoea issues *(n*=35) yielded consistent results.

3.7.1.3. Construct validity

Construct validity was based on a review of the literature on choice, sources of information for adults with sialorrhoea issues and access to care that informed the questionnaire and processes for this data collection. Therefore, the addition of relevant topic areas to the original questionnaire were essential to capture the areas for exploration of adults with sialorrhoea issues. The following three items were added to the original questionnaire: 'the presence of skin rash', 'frequency of mouth wiping' and ‘social avoidance by others’. This new scale is called the ‘Revised Sialorrhoea Impact Scale. In addition to this new scale, ‘management approach’, ‘effectiveness of management approach’ and ‘life satisfaction due to sialorrhoea’ were also added to the questionnaire survey to identify sialorrhoea management practice.

3.7.2 Qualitative data analysis process: Phases 1 and 2

One of the main challenges facing researchers during qualitative data analysis is to make sense of the data sets to identify the emerging themes during data analysis, which requires patterns to be identified and a framework to be utilised to ensure essential data is communicated effectively (Patton, 2002). As a result, in the qualitative phases of the study, the recorded data were fully transcribed into transcript documents which were subsequently coded and analysed for themes with qualitative software NVivo 12. Qualitative research software helps researchers to organize and analyse unstructured information. The field notes were also incorporated into the final development of the themes.

Initial thematic analysis was constructed using electronic and paper copies of the transcribed interviews. NVivo 12 software support was used thereafter. NVivo 12 was chosen to carry out data analysis, due to the characteristics offered by the software (such as automated coding, searchable annotations and hierarchical categories), the experience of the researcher and also due to the online support available. NVivo had two principal benefits for qualitative research within this study which included: efficiency and transparency. One of the primary challenges involving data analysis was “making sense” of large amounts of data, reducing information, identifying patterns and constructing a framework to communicate what the data revealed (Polit, *et al.,* 2001). The qualitative data analysis in this study followed thematic analysis framework adapted from Braun & Clarke (2006) and Nowell *et al.* (2017; figure 3.4). This analytical six stages coding framework approach was used to inform the research study, and was applied through robust analysis of data. Subthemes identified are described further in the narrative accounts in later sections.

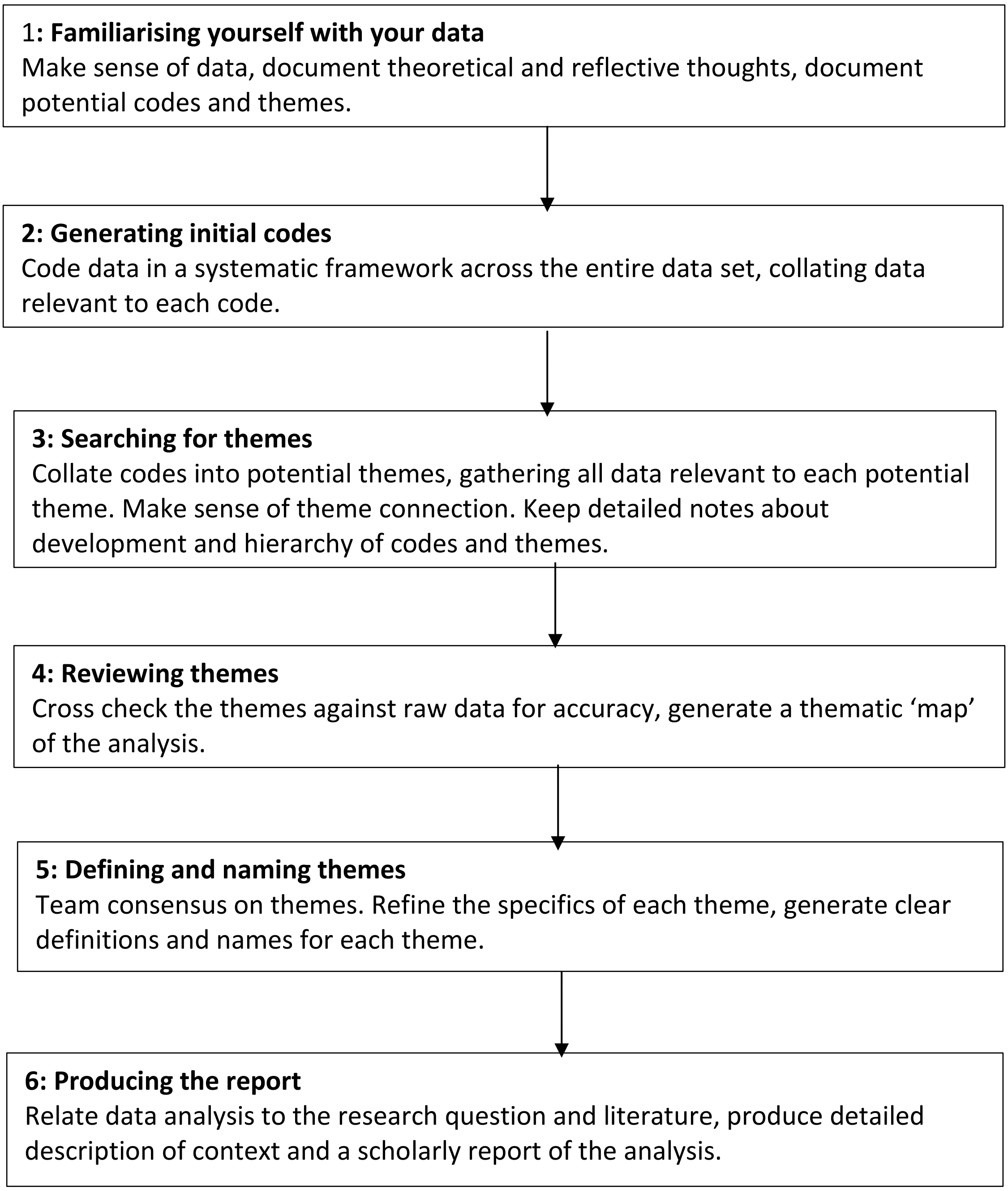


Figure 3.4 Qualitative data analysis process adapted from Braun & Clarke (2006) and Nowell et al. (2017).

3.7.2.1. Conceptual Mapping using NVivo

The Conceptual mapping in this study helped to explore meanings at different stages of analysis and was used to visually demonstrate processes such as stages of analysis or conceptual frameworks emerging from the study. Conceptual mapping is an important strategy in qualitative inquiry because it helps to draw connection with themes and concepts, it ensures that qualitative data is embedded in a particular context (Daley, 2004). Therefore, the visualised display of ideas, concepts and subthemes in concept maps illustrated the conceptual framework for the study and helped the process of data refinement, coding, and visualisation (Conceição *et al.*, 2017). Concept maps were an important strategy in the qualitative inquiry because they helped the researcher focus on meaning (Daley, 2004).

3.7.2.2. Database Queries

Data interrogation involved using standard database logic to ask questions of the data. This process is known as ‘running queries’. Such database queries using NVivo include the followings:

- Word Frequency Query- lists frequently occurring words or similar words and the number of times they occurred in selected documents or sections, enabled the identification of themes and subthemes. It also created a word cloud, tree map and cluster analysis. (See example below Figure 3.5)

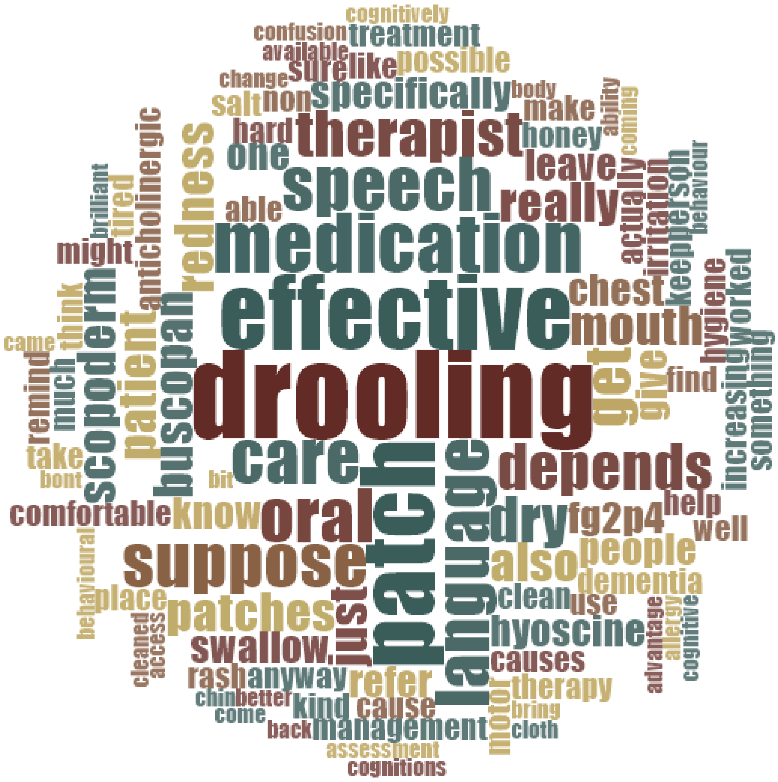


Figure 3.5 Word frequency text result NVivo12

- Text Search query- listed all the content that contains specific words, text or phrases which provided coding sources. It also included searching the literature for specified text. See example figure 3.6.

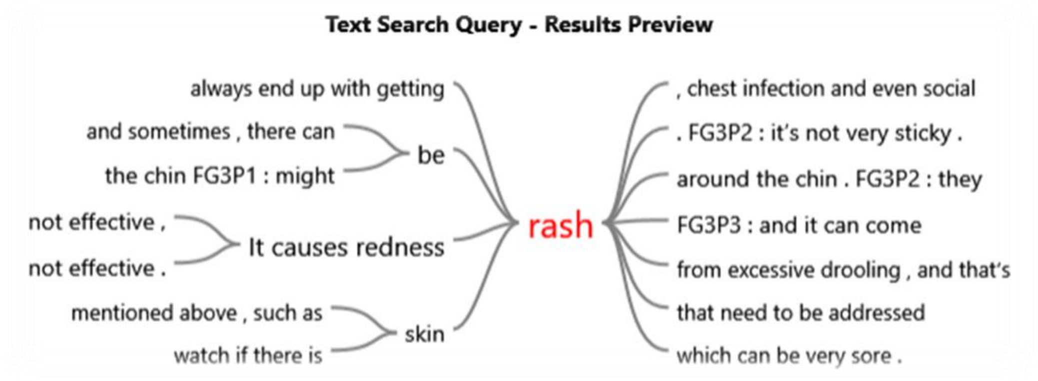


Figure 3.6 Text search query NVivo12

- Coding query-explored all content coded at specified nodes, a combination of nodes, or nodes with particular attributed value.
- Compound query-combined text search query with a coding query to search for text in or near coded content.
- Coding comparison query- compared coding done by two or a group of users.
- Group query- discovered items that are associated in a particular way with other items.
- Matrix coding query- tabulated the coding intersections between two lists of items.

3.7.2.3 Establishing rigour in qualitative phases

Rigour of research speaks of confidence in data, interpretation, and methods used to ensure the quality of a study (Pilot & Beck, 2014). Rigour in qualitative research requires that researchers continually strive to be fully accountable for their data collection, analysis, and interpretive methodologies, to ensure validity, credibility, trustworthiness, dependability, conformability, and transferability of the research (Tashakkori & Teddlie, 2010b; Onwuegbuzie &Teddlie, 2003). Therefore, it was important to establish rigour in the qualitative research phases of this study so that findings were accurate and credible in order to make an impact (Creswell, 2003). This principle was fostered strictly during the process of data collection and analysis. Furthermore, there was in-depth engagement of research material and data over a period of time at a variety of levels, from deep reading to broad overview following intense reflection so as to create insights of the research area. Subsequently, NVivo12 was utilised for data analysing adopting a thematic analysis approach to ensure quality and rigour of data analysis. The coding process using Nvivo12 is illustrated in figure 3.7 below. This coding process helped to carefully and systematically reduce the data to themes which addressed the research question, therefore, it ensured the transparency, consistency and accuracy of the identified themes.

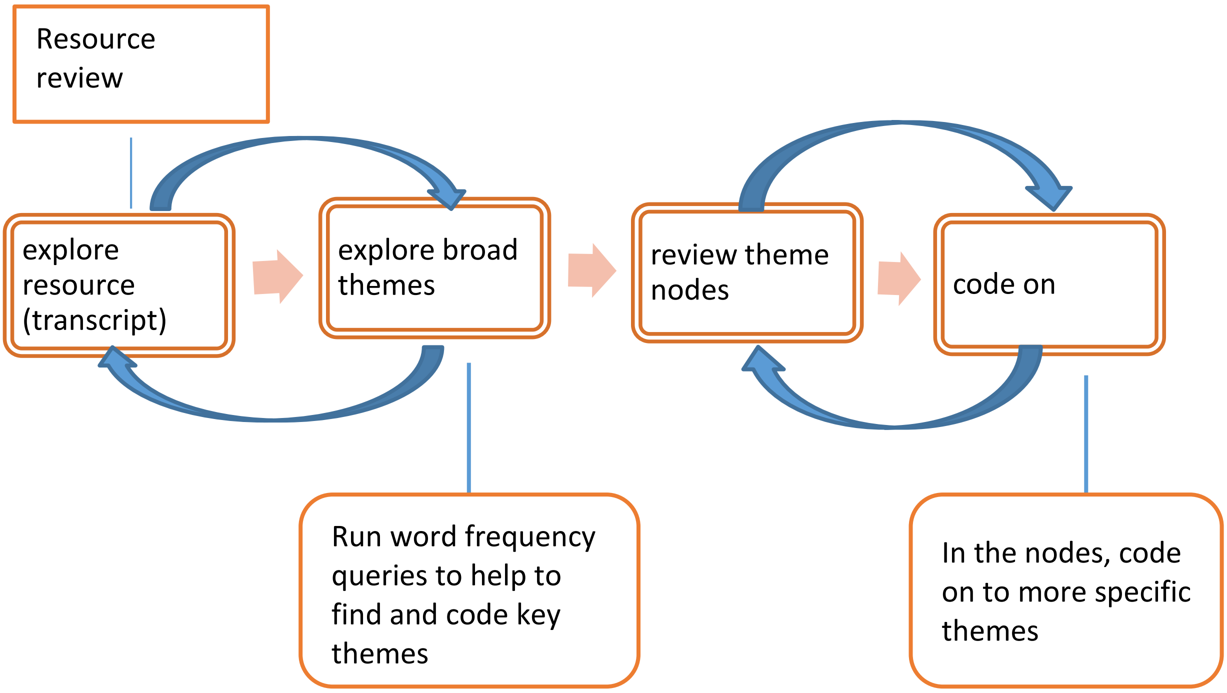


Figure 3.7 Theme coding process.

3.7.2.4 Transferability

Generalisation is not the goal of qualitative studies (Creswell, 2003), however, by the provision of clear and accurate descriptions of the research methods and contexts which were central to this study, and therefore the conduct of the research study at all stages, transferability of the study was enhanced. Guba and Lincoln (2005) suggested use of the term ‘transferability’ to judge the extent to which the findings can be applied to other contexts. Specific strategies were used to achieve transferability and included thick descriptions and purposive sampling (Byrne, 2001). In addition, rich and detailed descriptions of data provided the reader with enough information to judge the themes, labels, categories, or constructs of the study (Byrne, 2001), as well as supplying enough information to judge the appropriateness of the application of the findings. The following additional strategies were used in this study to enhance external validity otherwise known as transferability:

- A systematic approach was taken to the study following thematic analysis explained in section 3.7.2.
- Notes about ideas and decisions regarding development of themes were kept in NVivo.
- Provision of rich data with the aid of NVivo as a data management tool.

3.7.2.5. Credibility and trustworthiness with qualitative phases

The criteria for judging a qualitative study differs slightly from quantitative research. In qualitative design, the researcher seeks credibility, based on coherence, insight, and instrumental utility (Eisner, 1991) and trustworthiness. Guba and Lincoln (2005) described internal validity as credibility or trustworthiness. In addition, Lincoln and Guba (2005), also referred to reliability as dependability. Internal validity and conformability was enhanced in this study by the following measures.

- Digitally recording and transcribing focus groups
- Thematic portfolio/reflective diary
- Thorough engagement with data
- Providing verbatim examples of participants' accounts as evidence of interpretation
- Peer review and reflection

3.7.2.6. Peer reflection

Peer debriefing is a process of exploring one's analysis and conclusions with a colleague or other peers on a continuous basis (Robson, 2011). In the current study, different forms of peer debriefing were pursued. Firstly, the emerging findings were discussed at different intervals with academic supervisors and nurses working in older adult care. This review stimulated consideration of additional perspectives and explanations at various stages of the process of data analysis. It is believed that this aided the process of the search for meaning and patterns in the data (Long & Johnson, 2000; Jootun *et al.,* 2009).

3.7.3. Integration of quantitative data and qualitative data

Both the quantitative and qualitative data in this study addressed a common objective of evaluation of current sialorrhoea management practice in terms of the person-centred care approach. Phase 1 incorporated two concurrent strands, focus group interviews and questionnaires. Both types of data were collected at roughly the same time. Data analysis was initially carried out separately, and then a side-by-side comparison was carried out by jointly displaying both forms of data. Data analysis was carried out along data collection, and themes and findings were noted in memo notes for reference. Qualitative data were analysed via Nvivo12 and Quantitative data were analysed via SPSS 25. NVivo can quantify qualitative data via generating reports for frequency of themes within a sample, the percentage of themes associated with a given category of respondent, or the percentage of people selecting specific themes (Onwuegbuzie & Teddlie, 2003). Therefore, these quantified data from focus group interviews along with its emerging themes were then compared to the quantitative data collected separately from older adults. The scores from quantitative data measuring the severity and frequency of sialorrhoea and the impact of sialorrhoea on quality of life combined with finding from focus group interviews were interpreted and integrated to form findings. The two types of data provided validation for each other and created a solid foundation for drawing findings. These findings from phase 1 then informed phase 2 interview topics. The resulting themes from the subsequent in-depth one to one interviews were quantified via NVivo and integrated with the findings from phase 1 for final analysis and discussion. To illustrate the data integration with the two phases, a flowchart of the research processes and the research findings generated from the different phases of the study can be viewed in Figure 3.8. It portrays the sequence of the research activities, indicating the priority and implementation of the data collection and analysis procedures. It also lists the products or outcomes from each stage of the study and shows the connecting points between the quantitative and qualitative phases, as well as specifying the place in the research process where the integration or mixing of the results between the quantitative and qualitative phases occurs.

The challenges of mixed data integration is that it is very time consuming, and quantifying qualitative data also might lose depth and flexibility of qualitative data. Therefore, in order to develop a comprehensive understanding of the findings of the study, careful comparisons of data and detailed discussions with academic supervisors was carried out for accurate data interpretation and integration.

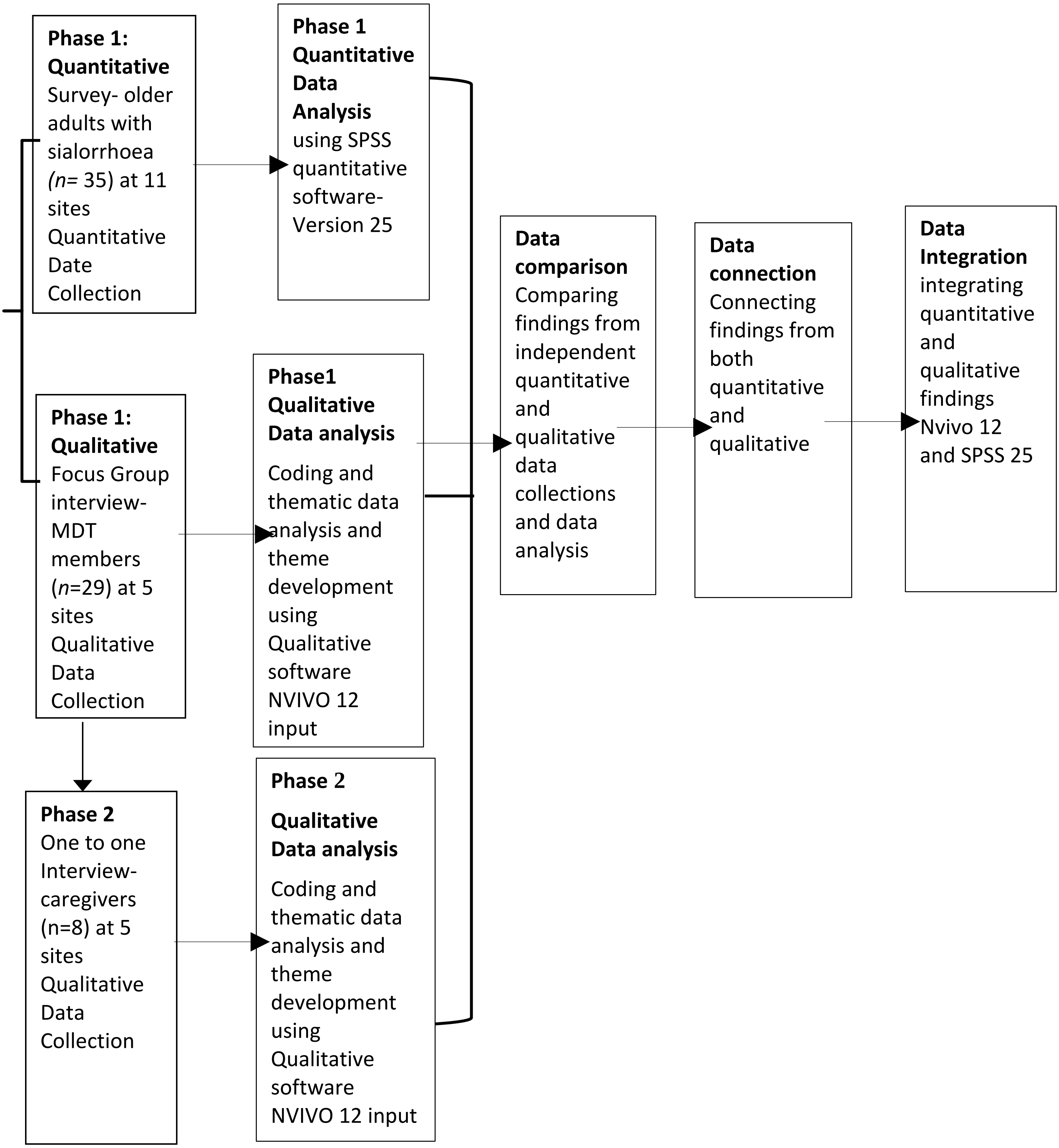


Figure 3.8 Data integration process.

3.8 Ethical considerations

This section explains the ethical considerations which arose from this study and the precautions taken. Ethics is defined as a system of moral values concerned with the degree to which research studies adhere to the professional, legal and social obligations to the participants of the study (Proctor &Renfrew, 2000). For the purpose of safeguarding human rights in research, the ethical principles of beneficence, respect for human dignity, confidentiality, vulnerability, justice and informed consent were all addressed in the following section.

3.8.1 Confidentiality and anonomyity

Confidentiality and anonymity are important ethical aspect for participants when partaking in research, information collected from participants in a study must be respected (Parahoo, 2006). The most likely source of harm in social research inquiry concerns the disclosure of participant's personal information (Denzin & Lincoln, 2005). It is the responsibility of the researcher to ensure that information received remains confidential throughout the proposed study. It was the researcher's intention to ensure confidentiality throughout the study and with this in mind, confidentiality in this study were maintained as described with the following precautions: the combined demographic information of participants did not make it possible for participants to be identified, every older adult who completed the questionnaire was assigned a code once they completed the survey and this was returned to the researcher. All of these measures aimed to reduce the risks to participants of being identified. Questionnaires were stored in a locked cabinet to maintain further confidentiality.

Although a coding system for participants was applied; workplace identification and the names of participants were not mentioned in final reports, however, with focus groups, it was not possible to maintain complete anonymity. In this case, the researcher assured participants that every effort was made to ensure that the data provided by them could not be traced back to them. Confidentiality was assured at the beginning of the focus group interview and it was explained that anything discussed remained confidential, and all participants were requested to respect each other's confidentiality and avoid discussing any related issues outside of the focus group.

One to one interview participants were assigned a code to protect confidentiality, and all data which related to each participant was kept strictly confidential. Anonymity by signing code for each participant and confidentiality were stressed at the beginning of every interview to assure participants' rights.

The recordings of focus group interviews and one to one interviews were destroyed once transcribed. Information from interviews and questionnaires were reported anonymously, using these principles, information provided by participants was reported in such a way that neither their identity nor location could be identifiable within the study. The written data were stored in a locked office at Waterford Institute of Technology (WIT) with a locked cabinet in the office. A WIT password protected computer was used with regard to protection of data. Storage of this data was in adherence with the WIT Computer and Network Security Policy (2018), particularly the clear screen and desk policy. A password protected computer was used with regard to protection of data when using computer software packages such as SPSS and NVivo.

3.8.2 Vulnerability and Capacity

This study was carried out in older adult residential care settings, therefore vulnerability became an ethical dimension. The older adult population are defined as vulnerable due to their frail health status, cognitive ability and available social support systems (Kim and Loren, 2008). In this study, the older adult participants had various neurological conditions that may have impacted their capacity. When carrying out research in the area of older adult care, the issue of capacity is one that needs to be considered. The World Medical Association (2013) advocate that whilst considering the importance of gathering rich data from the sample population, the researcher must also ensure that the welfare of all participants takes precedence and surpasses that of the interests of the study.

To ensure further protection of older adults, the healthcare team in the residential care setting had to determine the older adult's capacity to participate in the study. Capacity assessment was required for valid informed consent. Capacity refers to a person's ability to retain and understand the nature of the information provided in the decision-making process, it means the ability to make a specific decision at a specific time and specific situation (Hegde & Ellajosyula, 2016). Assisted Decision Making (Capacity) Act 2015 provides legally recognised decision-makers to support a person maximise their decision making power and it places a legal requirement on service providers to comprehensively enable a person make a decision through provision of a range of supports and information appropriate to their condition. Due to the fact that the researcher was seeking views of older adults who had neurological disorders, it was acknowledged that whilst these older adults had neurological conditions, it could not be assumed that they also had impaired capacity. Therefore, the research team met the individual and followed steps from HSE (2017) consent policy to ensured that residents understood clearly what the study involved and what they were consenting for which ensured valid consent. However, if their capacity was flagged by their healthcare team and after provision of all available supports and efforts in order to help residents to make decision, and residents still lacked capacity. Therefore, in compliance with the new GDPR regulations, these older adults were excluded from study unless they had legal representatives to sign the consent form. However, participants who regained their capacity had the right to decide whether they wanted to participate with the research study or not.

In order to ensure all participants felt secure and confident to take part in the study, all potential participants were fully informed about the research and the research methods being used which helped ease any anxiety that may have been present. Information sessions were held and information leaflets were distributed to all potential participants (Appendices F&G). In order to reduce the burden of filling the questionnaires, the layout and language of the questions used plain and layman language. Older adults who wished to participate in the study, but were unable to physically complete the questionnaire were offered assistance by the researcher or by their caregivers.

3.8.3 Informed consent

Informed consent is a significant issue for all research studies. All participants were provided with the relevant information through participants' specific information leaflets (Appendices F&G) and through information sessions which involved a presentation in order to obtain informed consent. The purpose, nature, benefits and risks of participating in the study were explained clearly. This study may not have had benefits for current residents, however it was explained that it might benefit future residents. There were no direct risks involved and any potential risks were kept at a minimum. This included reducing the risk of questionnaire burden by putting the questionnaire into a user friendly booklet for older adults. Participants were given contact details for the researchers and other related personnel and were given time (at least a week) after the information session to make a decision on whether or not to partake in the proposed study. Informed consent procedures and participant's rights in relation to the giving of consent were explained clearly, and any questions were answered to the satisfaction of the participants. Participants signed the consent forms (Appendices H&I) and returned the same to the researcher for consent to be valid.

Participants were informed of their right to withdraw from the study at any stage up to the collating of data without giving any reason. All data collection procedures commenced with the participants verbally confirming their consent along with their signed consent forms. This was in line with the ethical requirement of informed consent which related to individuals having the right to choose freely, without duress, whether or not they wished to participate with the research after being given sufficient information in a comprehensive manner regarding the research (Parahoo, 2006).

3.8.4 Justice

All participants were treated fairly which adheres to the ethical principal of justice. All participants were provided with all necessary information regarding the study and were not deceived in any way thus upholding the ethical principal of veracity. Those who chose not to participate were not disadvantaged in any ways.

3.8.5 Ethical approval

Ethical approval was granted from Waterford Institute of Technology Ethics Committee (21st September 2018; Appendix B) and from the Health Service Executive Regional Ethics Committee (8th October 2018, Appendix C). This required submission of an application form and research proposal to each committee was adhered to. An attendance for interview was carried out at the WIT Ethics Committee. During the interview, the Ethics Committee members provided feedback for dealing with issues revealed in the research process. The emergent phase of one to one interviews meant an addendum ethics approval submission was sought from the above two committees. Approval for Phase 2 was granted by Waterford Institute of Technology Ethics Committee on the 11th June, 2019 (Appendix D) and 5th July, 2019 (Appendix E) by the Health Service Executive Regional Ethics Committee. This was to ensure that the rights of the research participants were upheld through correct research practices.

3.8.6 Data protection

Data in this study were collected from focus group interviews, questionnaires and one to one interviews. Qualitative data analysis was carried out using a computer software package N-Vivo 12. Quantitative data analysis of the questionnaires was carried out using SPSS Version 25. All the data were digitally maintained on a password-protected computer in accordance with the Data Protection Acts 2018 and in keeping with the new GDPR Data protection policy. Therefore, the following procedure was employed for the storage and protection of data:

- All documents stored on the computer were constantly reviewed and cleared to include my documents, downloads, desktop and the recycle bin.
- A clear desk policy was ensured.
- The office and filling cabinet was kept locked.
- Ensured to lock the computer when leaving desk.
- When discarding documents, the correct method of destruction (any personal material and material of sensitive nature was shredded) was used.

- The relevant safety precautions were taken with regard to password protection/data encryption, when use of a laptop or memory stick to process data was employed.
- When accessing e-mails through a mobile device, all necessary reasonable steps were taken to protect data of a personal nature.
- Removed material containing personal data from photocopiers/printers in a timely manner
- Personal data was not disclosed to a third party.
- The security of documents of a personal nature was considered when carrying from one point to another.

3.9 Conclusion

This chapter provided a rationale for adopting a mixed method design using two study phases supporting a more complete multifaceted approach to the study and contributing to the rigour of the research study. The research processes involved in phase 1 and 2 were made explicit. It also explained data collection and analysis including the development and analysis methods for quantitative and qualitative data. It described issues in relation to the population and sampling, the choice of instruments, data collection and the data analysis to ensure an ethically sound and robust research endeavour to meet the research aims and objectives, and to answer the research questions. The following chapter 4 will present the findings from all phases of the study.

Chapter 4: Results

Introduction

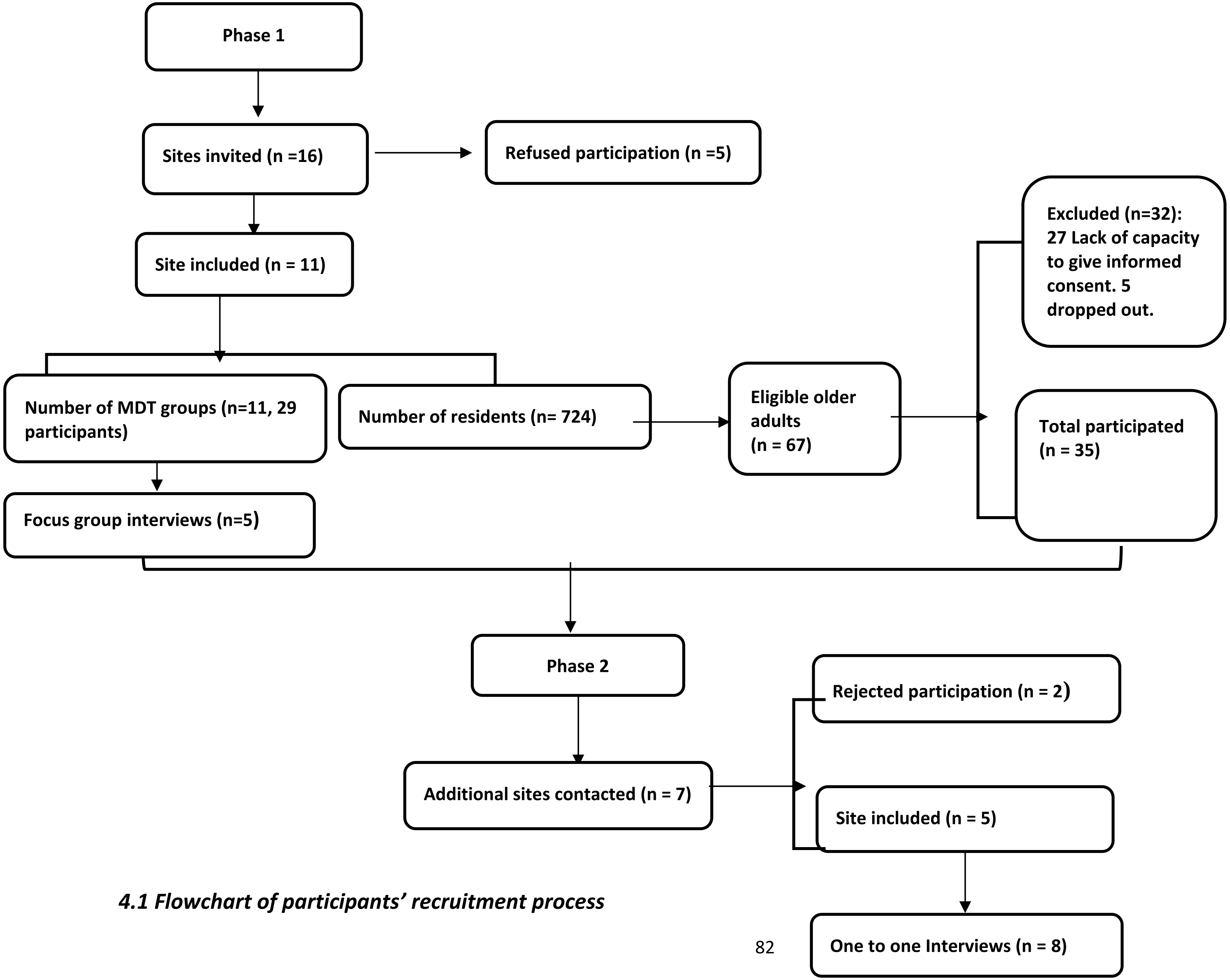
This mixed methods two phase study sought to identify and evaluate current sialorrhoea management practice in residential care settings within the Irish context. The study involved two key phases: a concurrent first phase with resident questionnaires and MDT focus group interviews; and a sequential second phase focusing on one to one interviews with caregivers. Study accrual and the data collection process are explained in Section 4.1. Section 4.2 presents the results from the exploratory questionnaire survey from older adults with sialorrhoea. Findings from five focus group interviews carried out in residential care settings in the South East region of Ireland are presented in Section 4.3. Section 4.4 presents findings from caregivers who look after older adults on a daily basis. A summary of the main findings of the study are presented at the end of the chapter. Integration of the findings involving all phases are then discussed in chapter 5.

4.1 Study accrual

This study was carried out in residential care settings in the South East region of Ireland. Recruitment and data collection took place from September 2019 to October 2019. Figure 4.1 provides an overview of the flow of participants through the study. The selection of the fieldwork residential settings was initially based on the geographical region selected in the project of which this thesis is a part, a project funded under the Nursing and Midwifery Planning and Development Unit, HSE South East. This region includes HSE state owned and private residential settings for the older adults. Through the desk-based study community hospitals and private nursing homes were identified by searching the size and function of the residential care settings based on their similarities and differences. Then initial emails were sent to 16 Directors of Nursing (DON) in residential care settings to recruit older adults with sialorrhoea and MDT members taking care of older adults with sialorrhoea, this was followed up by phone calls to the DONs. Eleven care settings agreed to participate, and 5 declined access.

In total 724 older adults were assessed for eligibility to participate, 67 older adults met the eligibility criteria (see Figure 4.1), but 27 of them were excluded due to the lack of capacity to give informed consent and 5 people withdrew from the study. Consequently, 35 survey questionnaires were collected from older adults with sialorrhoea.

Eleven out 16 of the residential care settings gave access to their sites. All multidisciplinary healthcare professionals working in these 11 residential care settings were given the opportunity to participate in the focus group interviews. Consequently, out of these 11 residential care settings, five of them organised MDT interviews including 28 MDT members and 1 older adult participated in the five focus group interviews. The second phase of this study became necessary at a later stage of the research due to limited access to older adults, therefore, seven more sites were contacted and 5 granted access, 8 caregivers participated in one to one interviews.



4.1 Flowchart of participants' recruitment process

4.2 Questionnaire survey

4.2.1 Demographic characteristics of older adults

Under the new GDPR regulation, there was limited access to older adults experiencing sialorrhoea due to lack of capacity and consequently issues involving informed consent. Hence, it became unachievable to reach calculated sample size of 95 participants and 35 questionnaires were completed in total.

The characteristics of older adults with sialorrhoea issues are displayed in Table 4.1 and 4.2. The mean age of older adults in this study was 77.74 (SD± 9.21), with 18 (51%) male and 17 (49%) female. Twenty five (71.4%) of the participants were verbal and 10 (28.6%) were non-verbal. Seventeen (48.6%) were ambulant and 18 (51.4%) were non-ambulant. Twenty six (74.3%) had no treatment for sialorrhoea and 9 (25.7%) had scopoderm patches. Nineteen (74.3%) participants did not receive non-medical management, 1 (2.9%) received oral care, 7 (20%) received Speech and Language Therapy management and 8 (22.9 %) were managed by wiping.

The main clinical conditions which the older adult participants presented with included dementia, CVA and PD which accounted for 25 (71.4%); 9 (25.8 %) had dementia, 7 (20%) had PD, 8 (22.9%) had CVA and 1 (2.9% 1) had both dementia and stroke.

Table 4.1: Demographic characteristics of older adult participants

Variables	Frequency (n)	Percent (%)
Age	Mean: 77.74	SD: 9.205
Gender		
Male	18	51.4
Female	17	48.6
Speech		
Verbal	25	71.4
Non-verbal	10	28.6
Mobility:		
Ambulant	17	48.6
Non-ambulant	18	51.4
Medication management		
None	26	74.3
Scopoderm patch	9	25.7

Non-medication management		
None	19	54.3
Oral care	1	2.9
SALT	7	20
Wiping	8	22.8

SALT, speech and language therapy.

Table 4.2: Clinical characteristics of older adults participants

Variables	N (%)
Bipolar disorder	1(2.9%)
Brain Tumour	2(5.7%)
CP	1(2.9%)
Dementia	9(25.8%)
Dementia; CVA	1(2.9%)
Fractured Vertebrae	1(2.9%)
Hypertension	1(2.9%)
MND	1(2.9%)
Osteoporosis	1(2.9%)
PD	7(20.0%)
Schizophrenia	1(2.9%)
CVA	8(22.9%)
Unknown	1(2.9%)

CP, Cerebral palsy; MND, motor neurone disease; PD, Parkinson's disease, CVA, Cerebrovascular Accident.

4.2.2 Comparing the Drooling Severity and Frequency Scale with the Sialorrhea Clinical Scale-Parkinson's Disease, Clinical Saliva Scale-Motor Neurone Disease and Revised sialorrhoea impact scale

To further confirm the reliability of the questionnaires being used in the study, Spearman's correlation coefficient was used to compare the relationship between items and subscales, using the data from the 35 residents recruited to the study. As shown in table 4.3, the lowest correlation was 0.267 and the highest was 0.991 with statistical significance ($p<0.01$) indicating moderate to strong correlations among the items and subscales. Therefore, the consistency of the scales was adequate. Spearman's correlation coefficient for the DSFS and the SCS-PD, the DSFS and the CSS-MND, and the DSFS and the 'Revised sialorrhoea impact' score were 0.817, 0.785, and 0.802 respectively, indicating positive correlations between scales. The strength of the relationships, using the criteria as recommended by Cohen (1998) were all large, as the correlation value was greater than 0.5.

Table 4.3 Spearman's correlation of items, subscales, and 'Revised sialorrhoea impact' scale

Item	Cough or choke due to sialorrhoea	Impact on eating and Speaking	Presence of rash due to sialorrhoea	Frequency of sialorrhoea	Social embarrassment	DSFS	SCS-PD	CSS-MND without NIV
Cough or choke due to sialorrhoea	1.000	0.485**	0.509**	0.325	0.324	0.267	0.469**	0.571**
Impact on eating and Speaking	0.485**	1.000	0.579**	0.670**	0.494**	0.587**	0.865**	0.881**
Presence of rash due to sialorrhoea	0.509**	0.579**	1.000	0.619**	0.474**	0.545**	0.692**	0.716**
Frequency of sialorrhoea	0.325	0.670**	0.619**	1.000	0.425**	0.863**	0.825**	0.804**
Social embarrassment	0.324	0.494**	0.474**	0.425	1.000	0.425	0.672**	0.657**
DSFS	0.267	0.587**	0.545**	0.863**	0.425	1.000	0.817**	0.785**
SCSPD	0.469**	0.865**	0.692**	0.825**	0.672**	0.817**	1.00	0.991**
Revised sialorrhoea impact scale Score	0.556**	0.853**	0.784**	0.854**	0.652**	0.802**	0.975**	0.981**

** $p<0.01$

4.2.3 Drooling Severity and Frequency Scale results

'Drooling Severity' and 'Drooling Frequency' scales were first scored separately and the overall result of the total DSFS scores from the 35 participants are displayed in table 4.4. With regard to severity of sialorrhoea, results showed that 60% (n=21) were rated to have moderate to severe sialorrhoea, 5.7% (n=2) were profuse. Sialorrhoea frequency results identified that 60% (n=21) frequently drooled, 11.4% (n=4) constantly drooled. The overall DSFS scores in this study ranged from 4 to 9, with Mean 5.83 and SD± 1.44. Two people (5.7%) were on the highest score. Based on the DSFS scores, these data indicated that the population typically exhibited moderate to severe sialorrhoea.

Table 4.4 The DSFS results

Drooling Severity score		
Level of Severity	**Number of Residents (n)**	**Percentage (%)**
Mild	12	34.3%
Moderate	13	37.1%
Severe	8	22.9%
Profuse	2	5.7%

<table>
<tr><td colspan="4">Drooling Frequency score</td></tr>
<tr><td>Level of Frequency</td><td>Number of residents (n)</td><td colspan="2">Percentage (%)</td></tr>
<tr><td>Occasionally drool</td><td>10</td><td colspan="2">28.6%</td></tr>
<tr><td>Frequently drool</td><td>21</td><td colspan="2">60.0%</td></tr>
<tr><td>Constantly drool</td><td>4</td><td colspan="2">11.4%</td></tr>
<tr><td colspan="4">Drooling Severity and Frequency Scale Score</td></tr>
<tr><td>Drooling Severity and Frequency Scale</td><td>Number of residents(n)</td><td>Percentage (%)</td><td>Mean ±SD</td></tr>
<tr><td>4</td><td>10</td><td>28.6</td><td rowspan="6">5.83 ±1.44</td></tr>
<tr><td>5</td><td>2</td><td>5.7</td></tr>
<tr><td>6</td><td>12</td><td>34.3</td></tr>
<tr><td>7</td><td>8</td><td>22.9</td></tr>
<tr><td>8</td><td>1</td><td>2.9</td></tr>
<tr><td>9</td><td>2</td><td>5.7</td></tr>
</table>

4.2.4 Sialorrhea Clinical Scale-Parkinson's disease results

This scale assessed the relationship between sialorrhoea and meal times, degree of diurnal and nocturnal sialorrhoea, difficulties speaking or eating, rate of severe sialorrhoea, and degree of social discomfort. SCS-PD scores range from 0 (minimum) to 21 (maximum) (Lloret *et al.*, 2007). Following consultation with academic supervisors, these scales were divided into three categories; (1-7), (8-14) and (15-21), with 1-7 indicating low impact, 8-14 indicating medium impact and 15-21 indicating high impact. SCS-PD scores (Table 4.5) in this study ranged from 2 to 18 (Mean 9.2, SD ±4.85). Just over 13 (30%) experienced low impact, 15 (42.9%) experienced medium impact and 7 (20%) experienced high impact. Results indicated the majority of participants (n=22; 62.9%) experienced a medium to high degree of discomfort due to sialorrhoea.

Table 4.5 The SCS-PD results

SCS-PD Score	Number of residents	Percentage %
1-7	13	37.1
8-14	15	42.9
15-21	7	20

4.2.5 Clinical Saliva Scale -Motor Neuron Disease without Non-invasive ventilation results

Two items were added to SCS-PD to assess the impact of coughing as a result of excessive saliva spilling into the patient's throat and the impact of excessive saliva on the use of non-invasive ventilation (NIV), however, the NIV item was removed in the current study. CSS-MND (without NIV item) score can add up to 24. Following consultation with academic supervisors, these scales were divided into three categories; (1-8), (9-16) and (17-24), with 1-8 indicating low impact, (9-16) indicating medium impact and 17-24 indicating high impact. Among these 35 participants (Table 4.6), scores ranged from 2 to 21 (Mean 10.1, SD ±5.43). Fourteen (40%) experienced low impact, 16 (45.7%) experienced medium impact and 5 (14.3%) experienced high impact. Data analysis indicated 21 (60%) of participants experienced medium to high impact of sialorrhoea.

Table 4.6 The CSS-MND results

CSS-MND Score	**Number of residents (n)**	**Percentage (%)**
1-8	14	40
9-16	16	45.7
17-24	5	14.3

4.2.6 Revised Sialorrhoea Impact Scale results

In this scale, the 11 items total score can add up to 33, where 1-11 indicates mild, 12-22 indicates moderate, 23- 33 indicates high impact. This categorisation was the results of consultation with academic supervisors. Participants' scores ranged from 2- 27 (Mean 12.86, SD±7.35). As can be seen in table 4.7, 16 (45.8%) were in the range of low impact, 13 (37.1%) were in the medium impact level and 6 (17.2%) were in the high range of impact. In total, over half (54.3%) of the participants experienced medium to high level of impact on quality of life due to sialorrhoea.

Table 4.7 The 'Revised Sialorrhoea Impact Scale' results

Sialorrhoea Impact Score	**Number of residents (n)**	**Percentage (%)**
1-11	16	45.7
12-22	13	37.1
23-33	6	17.2

4.2.7 Individual Sialorrhoea Item score results

Table 4.8 below illustrates the details of the number of participants who were impacted by individual items in the questionnaire (See Appendix K). Each item ranging from 0 (no problem) to 3 (severe problems; McGeachan et al., 2015). Results showed that 13 (37.1%) participants experienced different levels of rash around the mouth area due to sialorrhoea. The majority of participants (n=32; 91.4%) needed to wipe their mouths frequently. Sialorrhoea had affected 20 (57.1%) of the participants in the functionality of speech, with 10 (28.5%) participants having to swallow frequently in order to speak, 6 (17.1%) had trouble speaking and 4 (11.4 %) could not speak at all. Eating was also affected, with over half (n=20; 57.1%) of the participants being affected, 7 (20%) had to swallow frequently in order to eat, 11 (31.4%) had trouble eating and 2 (5.7%) could not eat at all. This indicated that sialorrhoea had affected more than half of the participants with their speech and eating functionalities. Eighteen (51.4%) of the participants had issues with coughing or choking due to sialorrhoea, indicating the risk of lung infection and therefore aspiration. Sixteen participants (45.7%) experienced some degree of social embarrassment.

Table 4. 8 Number of older adults reporting each score per item in the questionnaire survey (item details see Appendix K)

Item	**0**	**1**	**2**	**3**	**Total affected (n=35)**	**Percentage (%)**
Item1: Time of sialorrhoea	0	17	15	3	35	100%
Item2: Sialorrhoea at night	16	9	8	2	19	54.2%
Item3: Sialorrhoea at daytime	0	12	3	20	35	100%
Item4: Presence of rash due to sialorrhoea	22	1	7	5	13	37.1%
Item 5: mouth wiping	3	18	2	12	32	91.4%
Item6: Impact on speech	15	10	6	4	20	57.1%
Item7: Impact on eating	15	7	11	2	20	57.1%
Item8: Sialorrhoea times	1	14	14	6	34	97.1%
Item9: Social embarrassment	19	7	4	5	16	45.7%
Item10: Avoidance by others	31	2	1	1	4	11.4%
Item11: Cough/choke due to sialorrhoea	17	7	8	3	18	51.4%

4.2.8 Internal correlation of Individual Sialorrhoea Item score results

To analyse associations between items of the ‘Revised Sialorrhoea Impact Scale’, correlations were calculated between each item of the Revised Sialorrhoea Impact Scale’. As shown in Table 4.9, $p<0.01$ demonstrating statistical significance among items**.** Furthermore, table 4.3 above shows strong positive correlation between DSFS with SCS-PD, CSS-MND and ‘Revised Sialorrhoea Impact Scale’. These results demonstrate the positive correlations between the severity of sialorrhoea and the level of negative impact of sialorrhoea.

4.9 Spearman’s correlation of each item on ‘Revised Sialorrhoea Impact Scale’.

Item	Item 1	Item 2	Item 3	Item 4	Item 5	Item 6	Item 7	Item 8	Item 9	Item 10	Item 11
Item1: Time of sialorrhoea	1.000										
Item2: Sialorrhoea at night	0.330	1.000									
Item3: Sialorrhoea at daytime	0.449*	0.589*	1.000								
Item4: Presence of rash due to sialorrhoea	0.237	0.672*	0.565*	1.000							
Item 5: mouth wiping	0.343	0.557*	0.619*	0.560*	1.000						
Item6: Impact on speech	0.259	0.422*	0.497*	0.451*	0.555*	1.000					
Item7: Impact on eating	0.298	0.629*	0.691*	0.592*	0.596*	0.699*	1.000				
Item8: Sialorrhoea times	0.457*	0.457*	0.638*	0.548*	0.620*	0.511*	0.446*	1.000			
Item9: Social embarrassment	0.296	0.428	0.443*	0.474*	0.250	0.435*	0.413	0.408	1.000		
Q10: Avoidance by others	0.035	0.273	0.303	0.245	0.450*	0.180	0.378	0.268	0.407	1.000	
Item11: Cough/choke due to sialorrhoea	0.012	0.356	0.433*	0.509*	0.244	0.392	0.477*	0.318	0.330	0.064	1.000

* $p<0.01$

As shown in table 4.9, there is strong correlation between daytime sialorrhoea and night sialorrhoea. Both daytime and night time sialorrhoea have strong correlations with presence of skin rash and frequency of mouth wiping. The presence of skin rash is also strongly correlated with frequency of mouth wiping. Impact on speech is connected with frequency of mouth wiping. Impact on eating is strongly correlated with the following items: daytime and night time sialorrhoea, presence of skin rash, frequency of mouth wiping and impact on speech. Frequency of sialorrhoea is correlated with daytime sialorrhoea, presence of skin rash, frequency of mouth wiping and impact on speech. Cough or choking is correlated with presence of skin rash.

4.2.9 Sialorrhoea management results

In order to understand how sialorrhoea was managed, items were added to the questionnaire to explore views on the management approach used (figure 4.2) and its effectiveness (figure 4.3).

Thirty three participants answered the item relating to management, only 12 (36.4%) reported that they were looked after by a team, 11 (33.3%) stated they had no management, 5 (15.2%) were not sure and 5 (15.2%) attended their GPs. These data indicated only about a third of participants received a team management approach for their sialorrhoea.

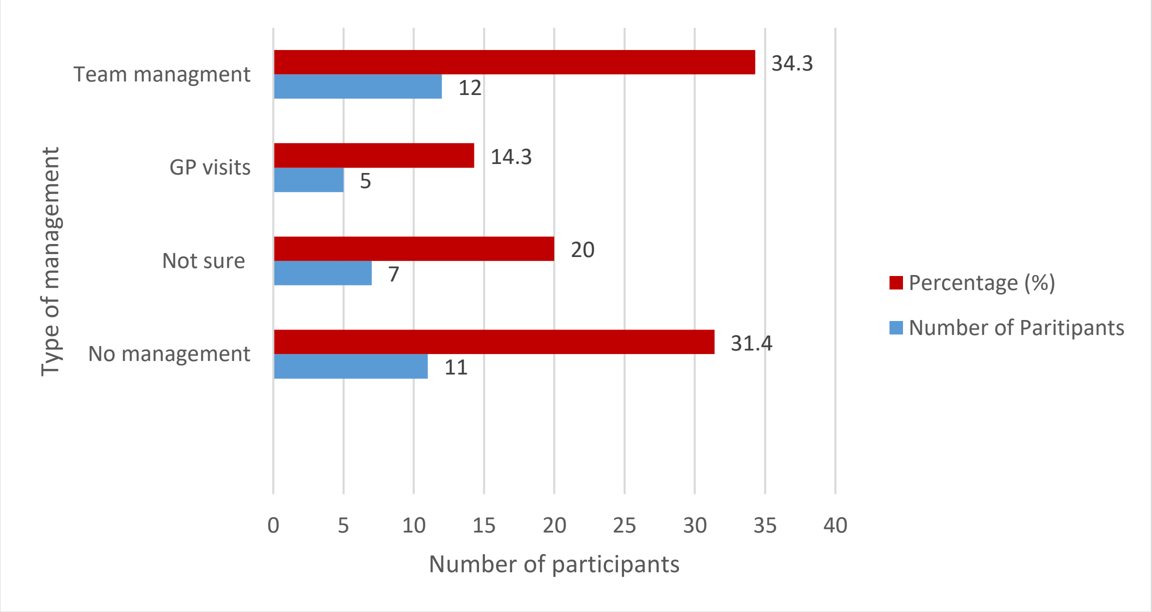


Figure 4.2 Sialorrhoea Management approach result

There were 25 (71.4%) participants who answered the question regarding treatment effectiveness of sialorrhoea, 13 (52%) reported no effect, 9 (36%) reported it worked sometimes, one participant reported it was working well and two reported it was working very effectively. The missing data were because 10 participants reported no management of sialorrhoea; therefore, they could not evaluate the effectiveness of management.

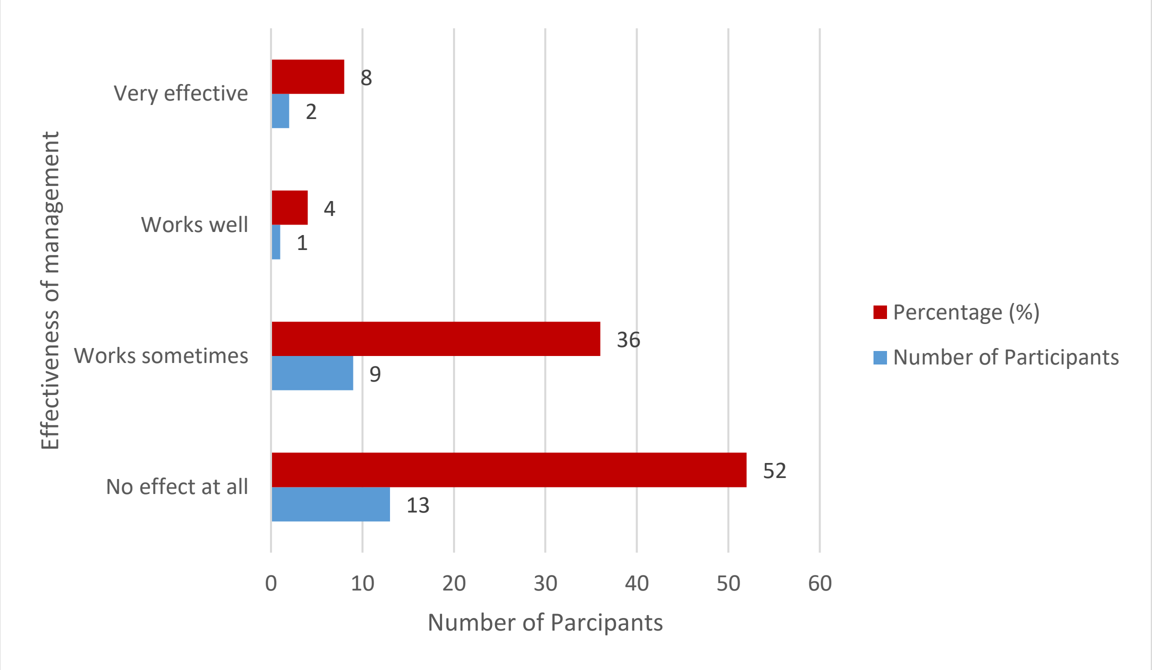


Figure 4.3 Effectiveness of sialorrhoea management result

4.2.10 Life satisfaction results

In order to find out how participants coped with sialorrhoea, an item regarding level of life satisfaction due to sialorrhoea (see figure 4.4) was added

Thirty-two out of 35 participants answered this question (see figure 4.4), with approximately two thirds (n=21;66%) of the participants expressing some degree of disatisfaction of life due to the issue of sialorrhoea.

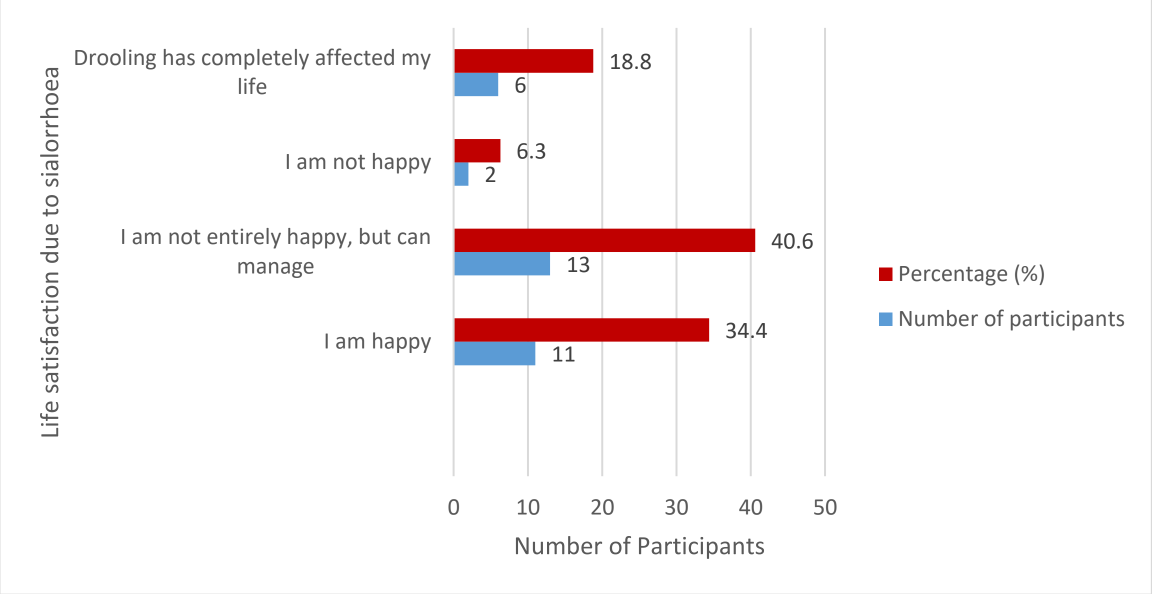


Figure 4.4 Participant's life satisfaction result

4.2.11 'Revised Sialorrhoea Impact Scale' score and life satisfaction analysis

In order to measure how sialorrhoea impacted participants' level of life satisfaction, a Kruskal-Wallis test was employed to analyse differences in the 'Revised sialorrhoea impact scale' scores between groups with different life satisfaction levels. This revealed a statistically significant difference in life satisfaction level in relation to sialorrhoea impact score across four different level groups (Gp1, n=11: I am happy, Gp2, n=13: I am not entirely happy, but I can manage, Gp3, n=2: I am not happy, Gp4, n=6: Drooling has completely affected my life), χ^2 (3, n=32) = 12.03, $p = 0.003$. See Table 4.10 below.

Table 4.10 Median Values for 'Revised Sialorrhoea Impact' score at different levels of life satisfaction

Level of life satisfaction due to sialorrhoea	**Mean**	**SD**	**Median**
I am happy	6.72	3.87	5.00
I am not entirely happy, but I can manage	14.76	6.39	12.00
I am not happy	22.50	6.36	22.50
Drooling has completely affected my life	15.83	6.79	16.50

*p=0.003

Further analysis was carried out using a non-parametric Mann-*Whitney U* to examine the difference between the 'Revised Sialorrhoea Impact' score at each of the different levels of life satisfaction. *Mann Whitney U* tests employing bonferroni correction were used to establish if there were significant difference among the groups of participants. Bonferroni correction was calculated by adjusting the *Mann Whitney U* test p values. In accordance with this, the *Mann Whitney U* test p value was multiplied by the number of comparison tests being carried out (6 tests) and was compared to alpha (0.05).

Table 4.11 Mann Whitney U test and P- value for 'Revised Sialorrhoea Impact Scale' scores between groups of life satisfaction analyses.

Between- group Analysis	Mean Rank	MWU	P-Value	P value (bonferonni correction)
I am happy-I am not entirely happy, but I can manage	7.91 16.38	21.0	0.002*	0.012*
I am happy -I am not happy	6.00 12.50	0.00	0.026	0.16
I am happy -Drooling completely affected my life	6.59 13.42	6.5	0.005*	0.03*
I am not entirely happy, but I can manage-I am not happy	7.35 12.25	4.5	0.171	1
I am not entirely happy, but I can manage-Drooling completely affected my life	9.65 10.75	34.5	0.701	1
I am not happy-Drooling completely affected my life	6.25 3.95	2.5	0.286	1

*P≤ 0.05

As can be seen from Table 4.11, in the comparisons to attain a statistically significant difference in the level of impact of sialorrhoea were the following two groups; the 'I am happy' with 'I am not entirely happy, but I can manage' group (MWU= 21.0; p=0.012), and 'I am happy' with 'Drooling has completely affected my life' group (MWU 6.5; p= 0.03). There were no statistical differences between the rest of the groups as can be seen in table 4.11 where p>0.05.

4.2.12. 'Revised Sialorrhoea Impact Scale' score and management approach analyses

The Kruskal-Wallis Test was performed to examine the relationship between 'Revised Sialorrhoea Impact' score among older adults with different sialorrhoea management approaches. It revealed a statistically significant difference in management approach across four different level groups (Gp1, n=11: no management, Gp2, n=7: not sure, Gp3, n=5: sometimes GP visits, Gp4, n=12: team management), χ^2 (3, n=35) = 10.62, $p = 0.002$. See Table 4.12.

Table 4.12 Median Values for 'Revised Sialorrhoea Impact Scale' score at different level of sialorrhoea management.

Sialorrhoea management approach	**Mean**	**SD**	**Median**
No management	9.09	6.83	6.00
Not sure	7.28	3.63	8.00
Sometimes GP visits	17.40	5.12	18.00
Team management	17.66	6.27	18.00

*p=0.002

Mann Whitney U tests employing bonferroni correction were used to establish if there were significant differences among groups of participants. Bonferroni correction was calculated by adjusting the *Mann Whitney U* test p values and keeping alpha at 0.05. In accordance with this, the *Mann Whitney U* test p value was multiplied by the number of comparison tests being carried out (6 tests) and was compared to alpha (0.05).

Table 4.13 Mann Whitney U test and P- value for 'Revised Sialorrhoea Impact Scale' scores between groups of sialorrhoea management analyses.

Comparisons	**Mean rank**	**MWU**	**P value**	**P value (bonferonni correction)**
No management- not sure	9.82 9.00	35.00	0.791	1
No management- sometimes GP visits	6.82 12.20	9.00	0.038	0.23
No management-team management	7.77 15.88	19.50	0.003	0.018*
Not sure- sometime GP visits	4.29 9.60	2.00	0.01	0.06
Not sure- team management	4.86 13.00	6.00	0.001	0.006**
sometime GP visits- team management	8.60 9.17	28.00	0.879	1

**P≤0.01

As illustrated in table 4.13, The two groups with statistical differences were ‘no management’ - ‘ team management’(MWU 19.50; p=0.018) and ‘not sure’ -‘ team management’(MWU 6.00; p=0.006).

4.2.13 Content analysis of open-ended question

Six short open-ended questions were asked in order to further understand the experience of older adults with sialorrhoea. All comments were subjected to thematic content analysis. The categories and sub-categories are represented by a quantitative breakdown of the comments which can be seen in figure 4.5. Three categories emerged from the analysis of the data: Impact of sialorrhoea on quality of life; Systematic care and management plan needed; Awareness of issue of sialorrhoea should be raised.

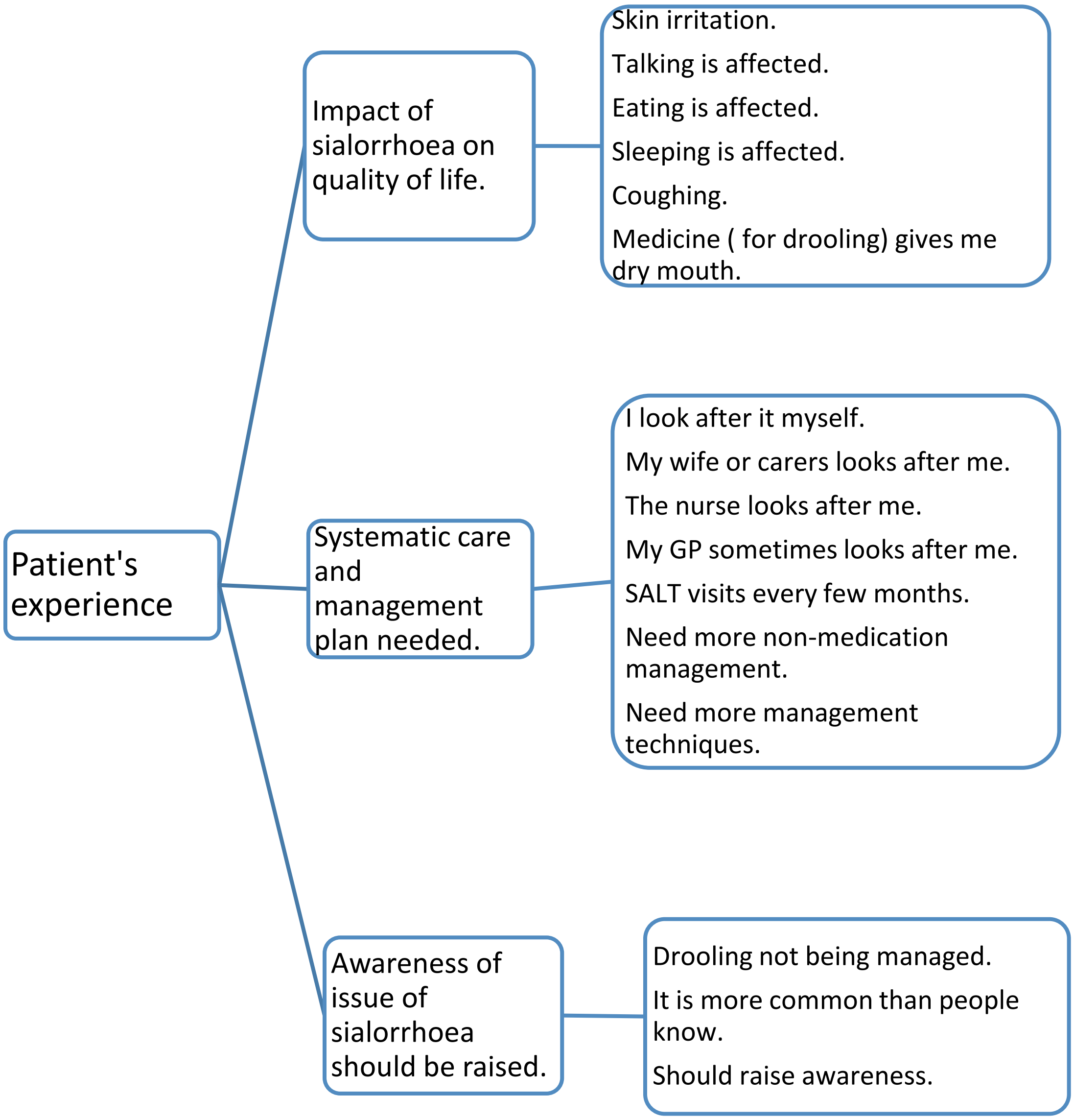


Figure 4.5: Emerging themes of resident's experience

4.2.13.1. Impact of sialorrhoea on quality of life

The presence of sialorrhoea hindering different aspects of life activities was also identified, which posed a negative impact on resident's quality of life. Sixteen (67%) out of 24 comments reported that sialorrhoea affected their daily activities and quality of life in different ways.

> *'My jumper may need to be changed 2-3 times a day. I always have to use tissues. Communication is becoming more and more difficult because I have to swallow constantly.'*-------P 29

4.2.13.2. Systematic care and management plan needed

There were 51 comments in total related to the management of sialorrhoea, 41 (80.3%) of these 51 comments indicated that sialorrhoea was mainly managed either by carergivers or residents themselves, sometimes GP and SALT visited them. It seemed that there was no systematic structure to sialorrhoea mangament. Participants reported that often they were left without management apart from wiping with tissue.

> '*I manage it myself with a box of tissues nearby during mealtime'*---P 7
>
> '*There is need for more non-medication management'*----P 3

4.2.13.3. Awareness of issues of sialorrhoea should be raised

Some participants expressed their concerns over the fact that sialorrhoea was not managed and there was no specific care provision regarding sialorrhoea. Some participants were not happy that they were only managed by tissue wiping either by themselves or their caregivers. Some of the participants directly pointed out that sialorrhoea was more common than people were aware and awareness should be raised. Fifteen (71.4%) out of 21 comments regarding these concerns indicated lack of awareness of sialorrhoea issues and a need for raising awareness of issue of sialorrhoea.

> '*It (sialorrhoea) is more common than people know'*----P 8
>
> *'(Healthcare team) need to raise awareness (of sialorrhoea)'*---- P 5

4.2.14 Summary of findings

The DSFS score results indicated participant experienced moderate to severe sialorrhoea. The 'Revised sialorrhoea impact' score indicated sialorrhoea had quite a significant impact on the quality and daily functionality of life. Physical discomfort like infection of skin around mouth area was quite a common side effect of sialorrhoea. Resident's eating and speaking was also affected. Risk of choking and chest infection were also a consequence of sialorrhoea. There were a degree of disatisfaction of life due to the issue of sialorrhoea. However, quite a significant percentage of residents were not managed regarding their sialorrhoea issue. Kruskal-Wallis tests and *Mann Whitney U* tests showed that sialorrhoea management approach and resident's life satisfaction level both were related to the 'Revised sialorrhoea impact' score. Thematic analysis findings of open-ended questions confirmed the negative impact of sialorrhoea. It also suggested the need for a structured management approach and the need to raise awareness of the issue of sialorrhoea with healthcare professionals working in residential care settings.

4.3 Qualitative Finding Phase 1- focus group interviews

4.3.1 Introduction

The main purpose of semi-structured focus group interview (FGI; see appendix J for topic guide) was to explore the views and perceptions of MDT health professionals regarding sialorrhoea management in order to identify the current practice protocol**.** The data collection started in January 2019 and lasted 5 months. In total, five focus group interviews were carried out in five hospitals within the South East region of Ireland, including twenty eight MDT members and one older adult participants. Participants included managerial nursing staff (6), professionals involved in direct care provision (13), medical consultant (1), allied health professionals (5), and older adults with sialorrhoea (1) Demographic information of participants provided a profile of the FGI participants summarised as follows in table 4.14.

Table 4.14 Professional profile of MDT members

Summary of professional profile of MDT members		**N**		**%**
Managerial nursing staff	Assistant Director of Nursing	2	6	20.6
	Clinical nursing manager	4		
Medical consultant	Consultant	1	1	3.4
Direct care provision professionals	Staff Nurse	9	14	48.2
	Healthcare assistant	5		
Allied health care professionals	Occupational therapist	2	7	24.1
	Physiotherapist	2		
	Speech and language therapist	2		
	Dietitian	1		
Older adults with sialorrhoea	Older adult with sialorrhoea	1	1	3.4

The identification process of qualititative categorial themes followed the steps of the thematic analysis framework (Braun & Clarke, 2006) in alignment with the research questions. As stated in previous chapter, the conceptual framework for this research study was person-centred care (the Health Foundation, UK, 2016), therefore, the dimensions of person-centred care were integrated while identifing themes. The coding process followed strictly the steps described in the previous chapter (section 3.7.2), and the process of theme coding using NVivo 12 is displayed in figure 3.7 in chapter 3. Rigorous and systematic reading and coding of the interviews was conducted, with themes recognised and outlined in table 4.15. These emerging themes together with the subthemes are described in the narrative accounts in later sections.

Table 4.15 Emerging themes and subthemes from MDT focus group interviews

Themes	**Theme 1**	**Theme 2**	**Theme 3**
	‘Saliva runs d*own their face, even goes under their chins’*. **Sialorrhoea compromising resident’s dignity.**	*‘We just manage from here, We don’t have any assessment tool’* **Ad hoc local management.**	*‘The MDT includes the doctor, nurse, carer and SALT, but it is not joined up here’* **Further integration of care required.**
Subthemes	• Physical Impact. • Psychological Impact. • Resident’s dignity compromised.	• Low awareness of the need for formal sialorrhoea assessment. • Apparent deficit in relevant knowledge and information. • External support not always in place. • Limited management techniques. • Challenges to maintain resident’s dignity.	• MDT management is not focused. • Care plan structure not aligned with management of sialorrhoea. • Sialorrhoea management surveillance guidance not evident. • Integrated care regarding sialorrhoea management is required

4.3.2 Theme 1: Saliva runs down their faces, and even goes under their chins.

‘Sialorrhoea compromising resident’s dignity’

One dimension of person-centred care is to treat patients with respect, including maintaining their dignity and quality of life which may be affected by their illness and treatment. In order to explore how sialorrhoea affects resident’s quality of life, MDT members were asked to discuss the impact of sialorrhoea on residents and how residents were coping with sialorrhoea. This theme ‘Sialorrhoea compromising resident’s dignity’ emerged from the MDT members’ discussion and four subthemes were identified as illustrated in figure 4.6. In identifying this theme, word frequency query was run by Nvivo12, concerns regarding resident’s skin infection, maintaining general hygiene and social embarrassment were reported by the MDT healthcare professionals involved in direct care provision and allied health professionals. The MDT members also expressed challenges in maintaining residents’ physical comfort and emotional support in care of older adults experiencing sialorrhoea. To conclude, the discussion with MDT members revealed that sialorrhoea had quite a significant negative impact on residents’ quality of life, both physically and psychologically, which subsequently compromised resident’s dignity.

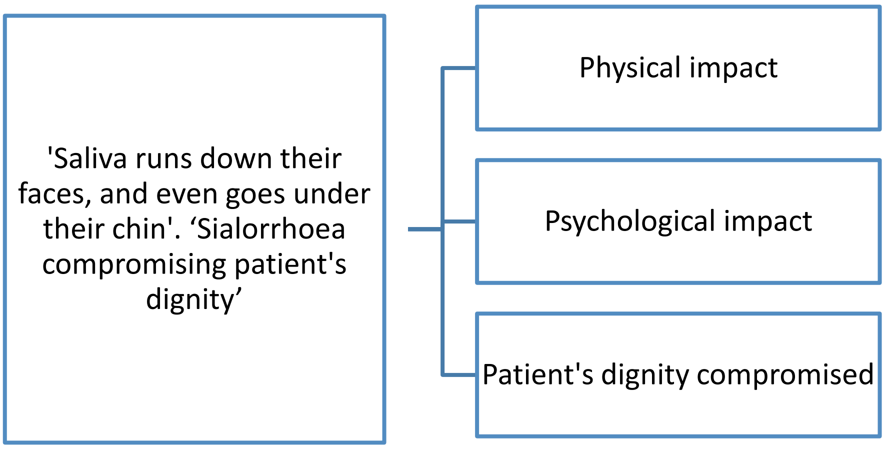


Figure 4.6 Theme 1: ‘Sialorrhoea compromising resident's dignity

4.3.2.1: Physical impact

Findings revealed that sialorrhoea caused physical discomfort. Thematic analysis displayed that skin infection and potential chest infection were the main physical impacts from sialorrhoea. In addition, the following accounts describe the details of the MDT members' views on how sialorrhoea impacts residents physically.

> *'They get kermises, and they are very sore. I suppose (the impact) it is their skin integrity, more risk of the chest infection'.*
>
> *(Focus group 1 Member 2)*
>
> *'Yes, (sialorrhoea causes) more risk of chest infection'.*
>
> *(Focus group 1 Member 4)*
>
> *'There might be rash around the chin'.*
>
> (*Focus group 3 Member* 1)

Apart from these physical discomforts, some members of the MDT suggested that sialorrhoea also affected resident's normal functionality and safety.

> *'It affects writing as well, they have to stopping writing to clean the drooling, it can cause safety hazard'.*
>
> (*Focus group 5 Member* 4)
>
> *'It can also be the balancing stuff, they don't want to hold the railing when go upstairs because he wants his hands ready to wipe, sometimes, they try to bend down, if drooling spills on the floor, and they try to bend down to clean it'.*
>
> (*Focus group 5 Member* 1)

Along with the discomfort caused by sialorrhoea, the side effects of treatment medication can also lead to physical discomfort, the MDT members were aware of and concerned about the associated side effects.

> *'The scopoderm patches, redness surround the patch, and kind of irritation, sometimes, if you give them Buscopan for chest, they can actually get dry mouth'*
>
> (*Focus group 1 Member* 2)
>
> *'Anticholinergic, hyoscine or whatever, in lots of situation runs the risk of increasing confusion and increasing cognitive impairment'.*
>
> (*Focus group 4 Member* 1)

Members of MDT also pointed out that side effects of medication for sialorrhoea could cause physical discomfort and safety issue.

> *'The patch can cause dizziness'.*
>
> (*Focus group 2 Member* 2)

4.3.2.2 Psychological impact

When asked about how residents were coping with sialorrhoea, another subtheme emerged from MDT members discussions suggesting that sialorrhoea also impacted residents emotionally and psychologically. Certain residents were very aware and conscious of the sialorrhoea resulting from their medical condition and were embarrassed about their appearance due to sialorrhoea.

> *'People with Parkinson, they are conscious of their drooling, it can be embarrassment'.*
>
> (*Focus group 3 Member 2*)

In some cases, residents found difficulty during social activity or meeting with other people.

> *'They kind of do not want to see visitors in the morning and evening times. He doesn't want to see them because he's looking like this. My resident has motor neuron disorder, he kind of stays in his room, so he is kind of shy to take some activity with other people'.*
>
> (*Focus group 2 Member 5*)
>
> *'I suppose eating in company then or coming into company is the difficult part of it'.*
>
> (*Focus group 5 Member 4).*
>
> *'It's a bigger problem for the resident, they often are embarrassed, they are very distracted by the drooling and trying to prevent it from happening'.*
>
> *(Focus group 5 Member 1*)

One member commented that physical appearance due to sialorrhoea could also affect family members' emotion.

> *'It is also hard for families to see them drooling yes, to see their loved one, mother or father to have drooling'.*
>
> (*Focus group 3 Member* 4)

4.3.2.3 Residents dignity compromised

While discussing impact of sialorrhoea on residents, MDT members also were concerned about residents' dignity. Due to the physical impact of sialorrhoea and residents' medical conditions, MDT members pointed out that sialorrhoea compromised residents' dignity. The physical impact from sialorrhoea, such as rash and being sore around the mouth area, as well as the physical appearance of saliva running down their face is associated with a lack of dignity. The psychological impact of social embarrassment and limitation of social activities due to sialorrhoea also compromise resident's dignity. To clarify this subtheme, MDT members commented as follows:

> *It's not dignified for him, his keeps his head to one side, and things on his clothes'*
>
> *(Focus group 3 member 4)*

Although the MDT members below did not mention directly that residents' dignity was affected, what was said clearly implied that resident's dignity was compromised.

> *'Saliva runs down their faces and even actually under their chin'.*
>
> *(Focus group 1 member 2)*
>
> *'Their neck postures are not great, like small baby I suppose, just collects saliva'*
>
> (*Focus group 5 Member* 1)

In summary, this theme explored how sialorrhoea impacts on quality of life among older adults experiencing sialorrhoea in residential care settings. The majority of MDT members (n=22) reported that sialorrhoea impacted older adults both physically and psychologically. First, sialorrhoea posed the potential for skin rash around the mouth area, and excessive saliva gathered under the chin and could also lead to the risk of chest infection. These physical changes due to sialorrhoea subsequently caused social embarrassment. Residents became conscious of the existence of sialorrhoea and felt embarrassed while meeting people, causing avoidance and limitation of social activities or events. Therefore, the findings from this theme revealed that sialorrhoea had a negative impact on residents' quality of life both physically and psychologically, and the impact of sialorrhoea on residents impose challenges for healthcare professionals.

4.3.3 Theme 2: 'We just manage from here, we don't have assessment tools'

'Ad hoc local management'

This theme was identified according to the accounts from MDT members regarding how sialorrhoea was managed in their workplace. According to person-centered care, residents should be offered personalised care and support. Word cloud analysis carried out by Nvivo12 regarding current practice of sialorrhoea management helped to identify the particular themes, text query and word query further confirmed the theme and subthemes. Subsequently, this theme was divided into four subthemes as outlined below.

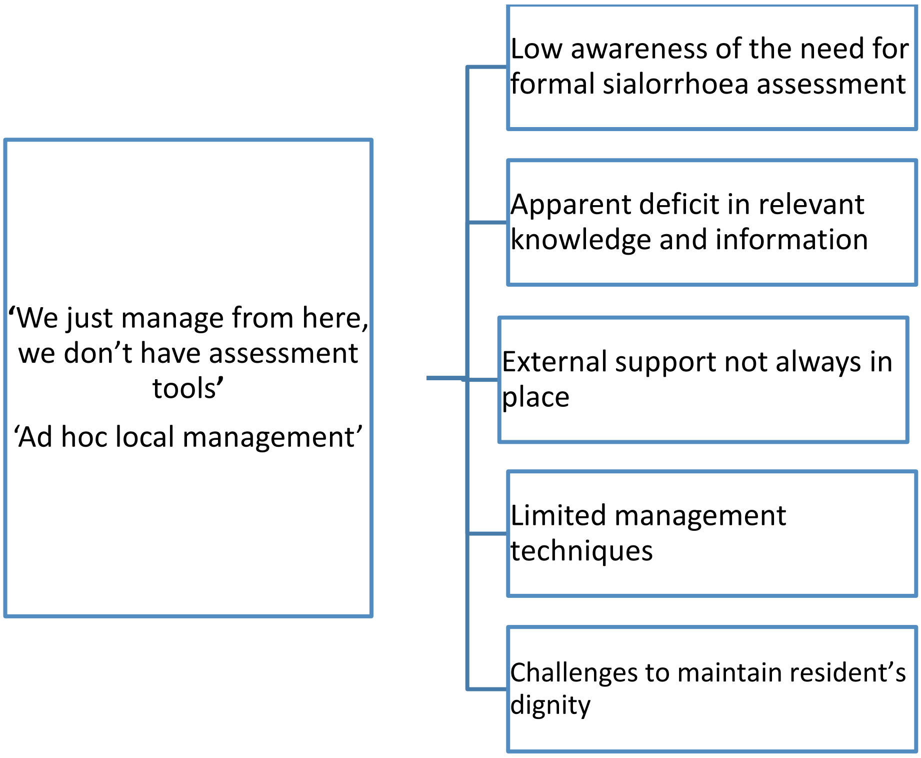


***Figure 4.7 Theme 2:* 'We just manage from here, we don't have assessment tool'**

4.3.3.1 Low awareness of the need for formal sialorrhoea assessment

During the focus group interviews, this theme 'Low awareness of the needs for sialorrhoea assessment' was identified while discussing how sialorrhoea was assessed. It seemed that none of the 28 MDT members were aware of any sialorrhoea assessment tools, and some members did not think there was a need to have the assessment tool. While discussing sialorrhoea assessment, some members commented as follows:

> *'There is no assessment, only visually observe, we never heard about it'.*
> (*Focus group 2 Member 1.2.3.4 and 5*)
> *'Maybe we do it naturally, maybe we notice more in the morning than in the evening, but never assessed'*.
> (*Focus group 2 Member* 4)
> *'We do have oral care plan with assessment tool, but drooling is not on the care plan'.*
> (*Focus group 3 Member* 4)

The comment from a speech and language therapist in the focus group below further confirmed the low priority and low awareness of sialorrhoea assessment.

> *'There isn't really a specific assessment for drooling, although we have dysphagia assessment, we will be looking at their lips, tongue, and their jaws, and then kind of observations if they are drooling'.* (*Focus group 5 Member* 3)

Regarding the necessity of sialorrhoea assessment, one assistant Director of Nursing during the interview commented that:

> '*we would have more people drooling in the past, I would say here at the present time, we don't have many drooling, we may have only one drooler, I would think there is one resident that drools in this place at the present time'.*
>
> (*Focus group 1 Member* 1)

This member definitely had met or taken care of residents with sialorrhoea in the past and acknowledged the fact that currently there was one resident with sialorrhoea at the time this interview happened, however she described how there was no need for an assessment tool.

> *'Because we don't need it (sialorrhoea assessment tool), if we had droolers, we would be looking at the assessment tool and we would be getting assistance, we have no droolers at the moment, it's not something we would focus on at the moment'.*
>
> (*Focus group 1 Member* 1)

Although it was clear there was low awareness of the need for sialorrhoea assessment, some MDT members did acknowledge the usefulness and benefit of having an assessment tool. One member commented on the benefit of having sialorrhoea assessment tools and expressed her wish to use an assessment tool.

> '*when I did the survey questionnaire, lots of the questions were asking a lot of details, which really kind of give us a best overall view, we could use the assessment tool to see what has been changing, what has been improved'*.
>
> (*Focus group 2 Member* 1)

Subsequently, MDT members expressed their interest and wish for sialorrhoea assessment tools.

> *'Definitely we need assessment tools'.*
>
> (*Focus group 2 Member* 3)

4.3.3.2 Apparent deficit in relevant knowledge and information

A deficit in relevant knowledge and information appeared as a theme during discussion regarding sialorrhoea assessment tools and different management approaches. When asked about the assessment tools, there seemed to be a lack of relevant knowledge as outlined below:

> *'We didn't know about it really, I suppose we could bring the assessment into our care plans and more education on it really'*.
>
> (*Focus group 2 Member 4)*
>
> *I didn't even know there is grading system.*
>
> (*Focus group 5 Member 4)*

Secondly, while discussing sialorrhoea management approaches and techniques, one MDT member, a senior occupational therapist, further confirmed there is deficit in the knowledge regarding sialorrhoea management.

> *'I don't feel like that know enough to comment. I don't feel like that I know enough about the standard'.*
>
> (*Focus group 5 Member 1)*

It also seemed that there is very little information about sialorrhoea due to a deficit of knowledge as one MDT member commented:

> *'That's the thing that you don't hear about and you don't talk about it. You don't hear as much about drooling'.*
>
> (*Focus group 3 Member 1)*

4.3.3.3 External support not always in place

Overall, there was strong evidence to support the benefit of external support, which many institutions took full advantage of, whether it was external professionals or simply support from family members. However, there was also evidence that external support was not always available or in place and in some cases it was underutilised. Regarding sialorrhoea management, the majority of the MDT members reported that the main external support is from speech and language therapists.

> *'We probably will get the speech therapist'*.
>
> (*Focus group 1 Member 2)*
>
> *'We usually refer to the speech language therapist'.*
>
> (*Focus group 5 Member 1)*

Some members reported family members as external support.

> *'The family is the external support'.*
>
> (*Focus group 2 Member 5)*
>
> '*Probably families would be much involved too, they would come to us and saying, Mum or Dad have drooling and the clothes'.*
>
> (*Focus group 1 Member 2)*

One member reported that some family members actively engaged in the management of sialorrhoea:

> *'We had a gentleman, his wife thought there had to be something to help, then came back with honey and tried honey and it worked'.*
>
> (*Focus group 3 Member 4)*

Some members commented on the external support from pharmacy regarding medication to manage sialorrhoea.

> *The pharmacy, we ring them up to see if they have update of the medication. Ask them if there is anything else we can give to the residents.'*
>
> (*Focus group 3 Member 4)*

However, some members reported either no external or limited access to supports.

> *'We have no external supports'.*
>
> (*Focus group 5 Member 2 and 4)*
>
> *'We don't have easy access to external support'.*
>
> (*Focus group 4 Member 3)*

4.3.3.4 Limited management techniques

Findings from focus group interviews with MDT members revealed that the main clinical management of sialorrhoea was the use of a scopoderm patch; non-clinical management was oral care and wiping. The majority of the MDT members recognised scopoderm patches had quite clear side effects and there was no clear agreement about its effectiveness.

> *'The patch is the only thing used and drooling is still there. It is not effective. It causes redness rash'.*
>
> (*Focus group 3 Member* 2)

> *'The Scopoderm patches. One person had allergy to it, one man kept knocking it off, and some people can get very dry.*
>
> (*Focus group 5 Member* 4)

> *'I suppose we would be bit limited with just patches, the scopoderm patches, redness surround the patch, and kind of irritation, resident didn't understand and taken them off. And you could find it stuck to somewhere else'.*
>
> (*Focus group 1 Member* 2)

One member suggested the scopoderm patch was very effective; however, she also expressed her concern over side effects and trouble in applying the patch.

> *‘we have found the scopoderm patch, the most effective in the management of drooling in our residence, but it causes the redness and irritation to the skin, the localised area, and it’s very specific where you can put the patch.*
>
> (*Focus group 2 Member* 1)

It is very clear from these reports that the scopoderm patch has quite significant side effects. Moreover, sialorrhoea can sometimes be caused by the side effect of psychiatric drugs; therefore, one member expressed concern about adding medication to manage sialorrhoea which may complicate the resident’s medical condition:

> *‘if we are concerned that the psychotic medication is exacerbating drooling, the first thing you really will look at balance of risk and benefit, adding medication like anticholinergic, hyoscine or whatever, in lots of situation runs the risk of increasing confusion and increasing cognitive impairment.*
>
> *(Focus group 4 member 1)*

Alternatively, MDT members discussed non-clinical management. Findings from focus group interviews showed that wiping and oral care were the main non-clinical or non-invasive management approaches for sialorrhoea management as shown in the following quotations:

> *‘Just wipe them (the mouths)’.*
>
> (*Focus group 2 Member* 5)

> *‘Just management, oral hygiene, oral care’.*
>
> (*Focus group 1 Member 2 and* 4; *Focus group 3 Member* 2)

One member also expressed her concern regarding oral care management of sialorrhoea:

> *‘They didn’t think about it, oral care is not controlling the problem’.*
>
> (*Focus group 3 Member 4)*

Another approach is to refer to speech and language therapist (SALT), however, reports from MDT members revealed that the role of SALT in managing sialorrhoea was mainly for swallowing difficulty management.

> *‘There is no non-medication treatment in place. SALT will decide to put thickener in their food and drinks for people with swallowing difficulty’.*
>
> (*Focus group 3 Member 1)*

One speech and language therapist further confirmed this:

> *'We do kind of oral motor, exercises and sensory stimulation, as a result then; it wouldn't be specifically target drooling, but drooling resolves.'*
>
> (*Focus group 5 Member 3)*

One other speech and language therapists also pointed out that there was other management approaches, but they were not used in long-term residential care settings.

> *'I know from the community clients, lots of advice would be around behavioural management. Non-medication would do a whole lot, but not in long-term care'.*
>
> (*Focus group 2 Member 2)*

However, some members of the MDT did comment on the difficulty of applying behavioural therapy.

> *'A lot of them have dementia, and they are not going to be able to have behavioural therapy'.*
>
> *(Focus group 3 Member 4)*

Although occupational therapists are involved in the care of older adults in the residential care settings, sialorrhoea management was not a specific task for them. An occupational therapist stated as follows:

> *'We would be looking at body posture anyway, but wouldn't be specifically for drooling. Realigning would be necessary anyway, but wouldn't be specifically for drooling'.*
>
> (*Focus group 5 Member 2)*

4.3.3.5 Challenges for Multidisciplinary team to maintain physical comfort

It was clear MDT members expressed their concerns over the apparent discomfort of sialorrhoea for the residents according to their appraisal. MDT Participants' comments in relation to the negative physical effects of sialorrhoea on residents revealed that they felt that there were challenges to maintain physical comfort for residents in the management of sialorrhoea. They discussed the barriers and challenges while taking care of residents with sialorrhoea and some members of the MDT said the following:

> *'Their skin integrity'*
>
> (*Focus group 1 Member* 4)
>
> *'I suppose to keep them as comfortable as possible'*
>
> (*Focus group 1 Member 1*)

For some residents, it is more of a challenge especially when sialorrhoea becomes a chronic condition. As one MDT member commented:

> *'The skin care. You would have seen people over the years would have developed fungal infection, probably would be very chronic drooling at that stage'.*
>
> (*Focus group 5 Member 1*)

The MDT members reported that residents were also affected emotionally and psychologically by the presence of sialorrhoea, and members of MDT were aware of the embarrassment residents experienced due to sialorrhoea. Some MDT member also mentioned the challenge of emotional supports to residents to cope with sialorrhoea.

> *'The challenge is to give them reassurance and make sure that they are not self-conscious'.*
>
> (*Focus group 1 Member 4*)

In summary, it seems that formal sialorrhoea assessment tools are not implemented in care of residents with sialorrhoea, and MDT members were not aware of the existence and need for the tools. The findings also revealed there was very limited management techniques known by MDT members. It was clear from the findings that sialorrhoea as a significant issue was not acknowledged enough and there was a lack of structured care pathway in care of residents with sialorrhoea.

4.3.4 Theme 3: 'The multidisciplinary team will be the doctor, nurse, carer or speech and language therapist, and it is not joined up here'.

'Further integration of care required'

Another dimension of person-centred care is to provide residents with coordinated care and support. During the discussion regarding management of sialorrhoea, there seemed some omission of integrated care provision, which was identified as a theme and was divided as in figure 4.8. Although MDTs exist in current residential care settings, there is no clear consensus regarding cooperation among members of MDT. Members of MDT were not joined together in order to provide integrated care.

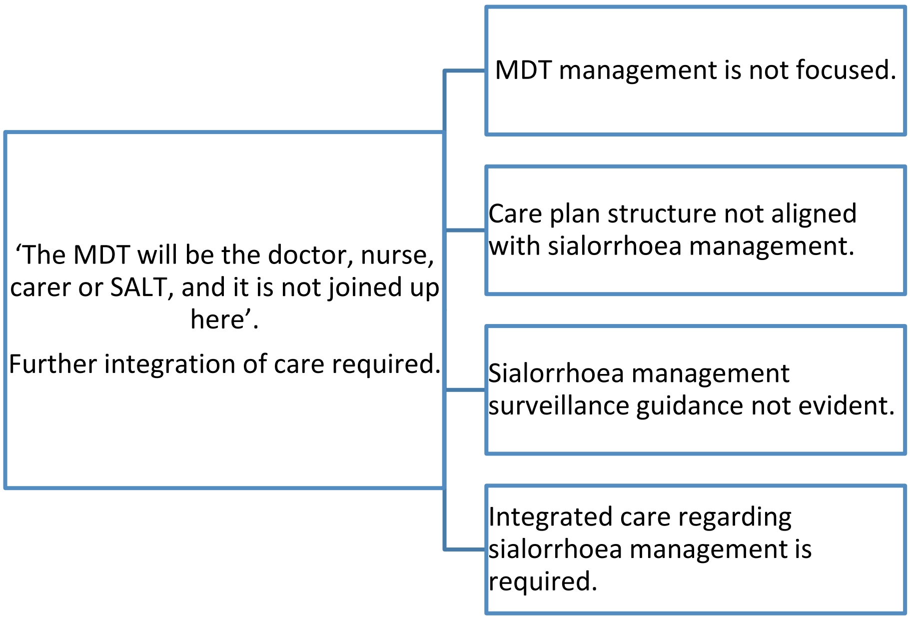


Figure 4.8 Theme 3: The MDT will be the doctor, nurse, carer or SALT, and it is not joined up here'.

4.3.4.1 MDT management is not focused

The majority of the MDT members reported that the management of sialorrhoea was mainly clinical based and a nurse led approach was sometimes taken.

> *'Maybe get the doctor involved as well. The doctor and it is nurse led'.*
>
> *'Mainly is the doctors. Then the nurses'.*
>
> (*Focus group 2Member 3)*
>
> *'Mainly the GP is the long term care, if it is an issue we would refer to speech language therapist'.*
>
> (*Focus group 2 Member 4)*

It seemed that although doctors were involved in the care of sialorrhoea, their main role was to give prescriptions for appropriate medications.

> *'The doctor decides to give the medication'.*
>
> (*Focus group 1 Member 4)*

As discussed previously, the speech and language therapist is part of the team, however their role in long-term residential care is not specified in the care of sialorrhoea, and the care of sialorrhoea would still be up to the GP or the nurse.

> *'In long term residential care, we only provide swallow assessment, we don't provide intervention, those residents there wouldn't have any management, and it would be on nurses, GPs'.*
>
> (*Focus group 5Member 3)*

One member also expressed the lack of cooperation of MDT members:

> *'the MDT should be the doctor, nurse, carer or SALT, and it is not joined up here and it wouldn't be MDT, the nurse would refer to the SALT, that it would be, and doctor would look after medication, so it's not MDT or joined up'*
>
> (*Focus group 3 Member 4)*

4.3.4.2 Care plan structure not aligned with sialorrhoea management

While interviewing the MDT members regarding their views on sialorrhoea management, 'care plan structure not aligned with sialorrhoea management' and insufficient structured care provision emerged as a subtheme. All the focus groups members (n=28) reported that sialorrhoea was not in the care plan, and there was no clearly structured care provision regarding sialorrhoea management. One of the members of the MDT commented:

> *'There is nothing there to guide us. My big thing is you would say to try this, and try this, you try everything, and find out what works and that would be helpful'.*
>
> (*Focus group 3 Member 4)*

Other members further confirmed the lack of structured care provision while providing care to residents with sialorrhoea.

> *'I certainly haven't come across very structured management pathway.'*
>
> (*Focus group 4 Member 1)*

4.3.4.3 Sialorrhoea management surveillance guidance not evident

While discussing the monitoring and surveillance system regarding sialorrhoea management and improvement of quality of life of residents, the focus group members reported that there was no systematic guidance to monitor care of sialorrhoea. Members discussed the lack of meetings for reviewing and monitoring sialorrhoea care:

> *'There is no team meeting to monitor'.*
>
> (*Focus group 3 Member 1)*

Some members commented that sialorrhoea was purely managed from the clinical perspective without a monitoring system.

> *'I don't think we have monitor system. It would be just clinical approach'.*
>
> (*Focus group 4 Member 1)*

It was pointed out that although in some places, there are reviews, it is undertaken by doctors for medication review only.

> *'Doctor will do review on medications every three months, looking to see if it is effective or not.'*
>
> (*Focus group 3 Member 4)*

Some hospitals would merely ask residents' feedback:

> *'We review from Resident's feedback'.*
>
> (*Focus group 5 Member 4)*
>
> *'We would ask residents if this is resolved'.*
>
> (*Focus group 5 Member 3)*

4.3.4.4. Integrated care regarding sialorrhoea management is required

When discussing views on future improvements in sialorrhoea management, focus group members all expressed their wishes for more structured care provision for the future management of sialorrhoea:

> *'Interdisciplinary collaboration, to be able to approach other disciplines, to be able to refer to, easier pathway of management'.*
>
> (*Focus group 4 Member 4)*

The only resident who attended the focus group interview expressed his wish for sialorrhoea management:

> *'There is low priority; it needs improvement, to raise awareness'.*
>
> (*Focus group 2 Member* 6)

In summary, this theme explored how sialorrhoea was managed by the MDT members. It was revealed by participants that there is a lack of integrated care provision in care of older adults with sialorrhoea in residential care settings. Participants discussed that there was a lack of cooperation among the MDT members while taking care of residents with sialorrhoea, like one participant mentioned 'it (The MDT) is not joined up here'.

4.4: Qualitative Findings Phase 2: one to one interviews with caregivers

The purpose of the Phase 2 study was to obtain further data regarding sialorrhoea management practice. Eight one to one interviews with caregivers (see table 4.16 for their demographic profile) were undertaken from June 2019 to September 2019. Four clinical nurses (*n*=4) and four healthcare assistants (*n*=4) participated in phase 2 of the study. The topic guide (Appendix M) for Phase 2 was based on the information provided by the Phase 1 exploratory survey with older adults with sialorrhoea and focus group interviews with MDT members. Phase 2 aimed to further investigate findings from focus group interviews and the questionnaire survey with older adults in order to develop a better understanding of the provision of care for older adults with sialorrhoea in the South East region residential settings of Ireland.

Table 4.16 Demographic characteristics of caregiver participants

Participant ID	Job title	Education
S1	HCA	Level 5
S2	Clinical nurse	Level 8
S3	HCA	Level 7
S4	Senior HCA	Level 8
S5	Clinical nurse	Level 9
S6	Clinical nurse/DON	Level 8
S7	Clinical nurse	Level 7
S8	HCA	Level 8

Findings from phase 1 with focus group interviews and the resident questionnaire highlighted that sialorrhoea had a significant negative impact on residents' quality of life and that there was a lack of a structured care pathway in the care of older adults with sialorrhoea in residential care settings. With this in mind, participants in one to one interviews were asked to discuss these issues further and identify possible changes. The overall findings of Phase 2 are presented here under the resultant themes (see figure 4.9).

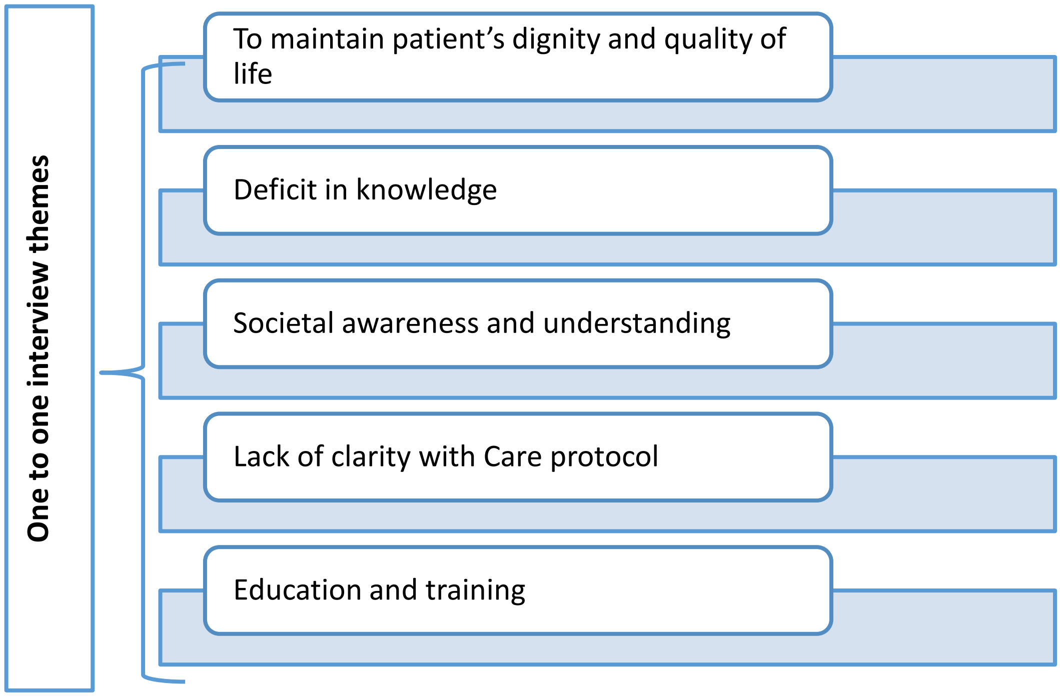


Figure 4.9 Resultant themes of one to one interviews

4.4.1: To maintain resident’s dignity and ‘quality of life’.

Findings in this phase revealed that care providers aspired to maintain residents’ dignity and quality of life, and they are vigilant in keeping residents as comfortable as possible. The caregivers’ role in care of the older adult with sialorrhoea in residential care settings was clearly stated and it is evident that these individuals are diligent in the provision of the best care possible for their residents.

> *‘As caregiver, we would like to have them to have clean and dry clothes. We also will watch if there is skin rash that need to be addressed by doctor. We would like to see our residents look comfortable’ (S 1)*

> *‘Every time when we have residents with those kinds of problems, we generally meet their needs quickly’* (S 7)

Findings also revealed that caregivers would provide the best care to residents although some residents do not have the mental capacity to be aware of their condition. They acknowledged that although some residents were not aware of their sialorrhoea, caregivers would still try their best to make sure their dignity was respected.

> *‘My own experience is that some of residents that have drooling episode, they wouldn’t have a clue what’s going on because their dementia is at the final stage. For them, it is an awful thing*

> *to say, but it wouldn't make difference to them if they drool or not. It is for us, the carers that would manage the keep their dignity.* (S 2)

All the caregivers (n=8) were fully aware of their role in the provision of care and were fully dedicated in their care giving. The following comment further revealed that caregivers were fully aware of their role to care and that they are providing the best care to maintain resident's dignity.

> *'it depends on residents, some residents are very aware of their drooling and try to wipe themselves, unfortunately majority of the residents have no idea about their drooling problem, and in this case, it is entirely up to staff to ensure their dignity is respected. For example, to make sure to change their clothes and wipe them often to make sure they are comfortable'.* (S3)

4.4.2 Deficit in relevant knowledge

Although caregivers were all fully aware of the issue of sialorrhoea and were empathetic to residents with sialorrhoea, some expressed the frustration of lack of competence and knowledge to manage sialorrhoea. Eagerness and passion to learn and share knowledge regarding taking care of a resident with sialorrhoea is evident.

> *'I have hand on experience, but doesn't mean that I am knowledgeable of everything. There is theory and practice I don't know like experts would know, so we would like to learn and share with everyone'.* (S 2)

To understand the underlying cause of sialorrhoea is important to help to alleviate and manage sialorrhoea. Subsequently, some caregivers expressed the difficulty and barrier of not knowing what to do regarding taking care of sialorrhoea.

> *'A lot of time people don't know what's causing the drooling and you know it's going to be managed differently for the causes. It's just people don't know what to do a lot of time, all we do is wiping'.* (S 4)

4.4.3 Societal awareness and understanding

In terms of awareness of sialorrhoea, Phase 1 findings highlighted the need to increase awareness; Phase 2 findings also revealed there is clear need to raise awareness of sialorrhoea from both societal and professional perspectives. During discussion, participants accepted that sialorrhoea is more common than people are aware of and that the impact of sialorrhoea is more significant than what people realise, which leads to a low priority for sialorrhoea management.

> *'There is lack of awareness as it is just seen as part of their care and not highlighted. All we do is to wipe residents or change their clothes. I think this needs to be highlighted as it can lead to other issues if not addressed, there must be some way to improve this'*. (S1)

Apart from calling for more awareness of sialorrhoea, the majority of the caregivers also commented on the benefit of increasing awareness in general.

> *'Drooling is actually more common than people think; it would be very beneficial for residents, the sooner they get treated, the better for their dignity and quality of life'*. (S 3)

Participants stated that the issue of sialorrhoea is underestimated and it is not been given enough attention, as some caregivers further confirmed that sialorrhoea and its underlying causes were not being discussed enough.

> '*I think it is something which is not discussed a lot, there is a lack of awareness of why it is happening'*. (S 6)

Therefore, some participants expressed they were happy to be included as part of this study, and could appreciate the benefits that this study would create for their residents. They expressed their gratefulness and excitement of being able to contribute. Sialorrhoea was something that the care givers felt would happen to everyone and therefore, people should be made of aware of it.

> *'It is a very good topic to bring up, it is something we don't discuss a lot. It is something very interesting; it is something that people should be made aware of. It is something everyone will meet at some stage*.' (S 7)

One caregiver also expressed her gratefulness of participating in this study from her personal experience and caring practice perspectives.

> *'I am grateful that you have this study, my own father before he died, he drooled a lot and he had stroke. It's nice to know if you are in health caring business, you would like to know all the areas of aspects'. (S 2)*

Caregivers provide hands on care and are more vigilant about a resident's condition; some caregivers advocated that full awareness and vigilance of sialorrhoea should be at the same level across all healthcare professionals.

> *'Maybe they are severe in our eyes, but not in the eyes of SALT view or the GP. Other than that, just constantly clean up around the mouth area'. (S 4)*

4.4.4 Lack of clarity of care protocol

Whilst it was expressed from Phase 1 and 2 that MDT members and caregivers worked to their best ability and standard in order to provide care for residents with sialorrhoea, findings from these interviews with caregivers revealed that it was unclear for them as to what care protocol they were following.

> *'I am not well aware if we have protocol of drooling or not, our crowd is very big, 79 residents, it could be one person or maybe none at all. Maybe this is something we should look after in the future, we could recommend for the management to have the policy or protocol for the drooling'*. (S 2)

It was expressed that it seems to be unclear what management plan is in place, and there seems to be no guideline for caregivers to follow while providing care for residents with sialorrhoea.

> *'If GP becomes involved, we are telling them the severity of it and how interrupting their lives, but we are not given an exact direction of what to do'.* (S 4)

Caregivers expressed their concerns of not having guidelines to follow; therefore, some of them expressed the need to have sialorrhoea included in the care plan.

> '*At the moment, we just include in their care plan and set time for oral care over the day, but I think this should be more structured' (S 6)*

Some caregivers expressed the need for detailed care procedure for sialorrhoea, therefore, some of them pointed out the lack of structured step-by-step care plan.

> *'We don't have structure care plan, like step by step, where it is an issue, where it is part of the care plan package'. (S 7)*

4.4.5 Education and training

It was acknowledged in the interviews with caregivers that there was poor information and education provided in relation to sialorrhoea management. In addition, a clear desire for education and training was acknowledged in interviews with all caregivers (n=8). All the caregivers expressed the necessity for the provision of education and training regarding sialorrhoea.

> *'There should've ongoing training as any help or advice on maintaining drooling could help to improve'*. (S 1)

Some caregivers also pointed out that education and training were important for raising awareness.

> *'I think something, maybe more training or awareness about it, what we can do, or protective clothing or something for it'. (S 8)*

One caregiver recommended there should be ongoing training regarding sialorrhoea management in order to meet the need of residents with different underlying causes of sialorrhoea.

> *'Every season, as the generation goes along, and the illness and disease are different, I think there should be ongoing training, so that we keep learning'*. (S 2)

Caregivers also expressed there was a need to have sialorrhoea management as part of training for healthcare assistants.

> '*There should be more education around it, a lot of new staff come on, are literally just finishing Fetac healthcare course, and this is not covered in it, and they don't know the causes or anything why, and to just come out of a course to a healthcare assistant and not to know the causes of drooling, I think it's a terrible lack of education in that area'*. (S4)

One clinical nurse who is also the DON in a residential care setting acknowledged that healthcare assistant training should include training on sialorrhoea, but at the same time, nurses would help to provide training to healthcare assistants in order to provide better care to residents.

> '*I see with care assistant, their qualification is Fetac leve5, level 6, they don't really know why is happening, they can't explain it. We as nurse are trying to educate them as what can be done for the residents to promote comfort and definitely at meal times'*, (S 6)

In summary, whilst participants revealed that they are providing the best care they can to older adults with sialorrhoea, finding also revealed a lack of societal and professional awareness and understanding in relation to sialorrhoea. Findings also identified a lack of expertise and professional knowledge, lack of structure of care protocols; insufficient information and in service education are clearly presented in the findings. Furthermore, findings revealed the need to fully understand and address the issue of sialorrhoea as a matter of urgency in order to provide comprehensive care to residents with sialorrhoea.

Although caregivers are reported as being vigilant while taking care of residents, it was revealed that the provision of guidance in relation to how to provide specific care for sialorrhoea in residents gets little attention in clinical practice. It was reported that there is no guideline or direction for caregivers to follow and no care plan to provide structured care for sialorrhoea.

4.5 Summary of overall findings (phase 1 and 2)

In conclusion to the chapter, the Phase I Strand 1 questionnaire survey sought to measure the participant's sialorrhoea severity and frequency and how sialorrhoea impacts on quality of life, and subsequently to explore sialorrhoea management practice. There were a number of key findings from this phase. The majority of the older adult participants had moderate to severe sialorrhoea. Over one third of the older adults in this study experienced skin rash around the mouth area and the majority had to wipe their mouths frequently. Over fifty percent of the older adults had impaired speech and eating difficulties due to sialorrhoea. Half of the older adults had to swallow frequently, which might cause the risk of lung infection. Just under fifty percent experienced some degree of social embarrassment. Regarding sialorrhoea management, the majority of older adults managed either by self-care or their carers wiped their mouths, about 1/3 of the participants were looked after by a healthcare team, among these, only small number of them reported that the management was effective. Approximately 2/3 of the older adults reported low levels of life satisfaction. Open-ended questions revealed that there was a lack of management choice and residents asked to raise awareness of the issue. Quantitative data analysis also revealed that the degree of impact from sialorrhoea did affect the level of life satisfaction and team management reduced the degree of impact from sialorrhoea.

In Phase 1 Strand 2 of the study, multidisciplinary healthcare team members participated in semi-structured focus group interviews. The purpose of the focus groups was to explore and elicit a deeper understanding of the older adults experience and the views of the MDT members regarding sialorrhoea management practice. All the MDT members acknowledged the negative impact of sialorrhoea on quality of life, which is consistent with phase 1 strand 1 questionnaire findings. The key categories that emerged from the interviews were the general lack of awareness of sialorrhoea and under structured care provision.

Phase 2 sought to further understand findings from Phase 1 of the study. Semi-structured one to one interviews were carried out with caregivers (nurses or healthcare assistants) to explore their views and perceptions of sialorrhoea management practice. Findings further confirmed Phase 1 findings; sialorrhoea had significant negative impact on older adults physically and psychologically and there was lack of structured guidelines or care protocols in place in the care of sialorrhoea. The Integration of the findings involved all phases (See Table 4.17) and a critical discussion of these results is provided in the next chapter. The findings with regard to each of the study objectives will be discussed further.

Table 4.17 Integration of findings from both quantitative and qualitative data

	Negative impact of sialorrhoea	Management of sialorrhoea	Suggestion for sialorrhoea care provision
Findings	• Physical impact: phase 1 quantitative and open ended questions, qualitative phase 1 and phase 2. • Psychological Impact. Phase 1 quantitative, qualitative phase 1 and phase 2. • Impact on quality of life: phase 1 quantitative and open ended questions, qualitative phase 1 and phase 2.	• No formal sialorrhoea assessment tools and procedures: phase 1 quantitative and open ended questions, qualitative phase 1 and phase 2. • Insufficient MDT management: phase 1 quantitative and open ended questions, qualitative phase 1 and phase 2. • Low awareness of sialorrhoea with low priority: phase 1 open ended questions, qualitative phase 1 and phase 2. • Low effectiveness of management: phase 1 quantitative and phase 2 qualitative phase.	• Structured guidelines or care protocols needed: qualitative phase 1 and phase 2. • Education and training needs for healthcare professionals: qualitative phase 1 and phase 2.

Chapter 5: Discussion

Introduction

This study set out to explore sialorrhoea management practice in the South East of Ireland. This chapter presents a discursive interpretation and integration of the findings from the two phases of this study in the area of sialorrhoea management. The findings will be discussed in association with the current literature. A person-centred care model created by the Health Foundation, UK (2016) as outlined in Chapter 3 section is used as a guiding framework. This framework facilitates the discussion of the significance of the findings for clinical practice and for all healthcare professionals involved in the provision of sialorrhoea management whilst also considering the findings contribution to the existing literature.

This is the first study to evaluate current sialorrhoea management practice among older adults in residential care settings in the South East of Ireland. Phase 1, which involved the questionnaire survey (n=35) and five focus group interviews (n=29) provided a rich source of information which was explored in greater detail during the subsequent phase 2 of the study. Phase 2, which included one-to-one interviews with caregivers (nurses and healthcare assistants; *n*=8), provided additional insight to the findings from both the questionnaire survey and focus group interviews.

The findings are discussed under the following three main headings:

- Current management practice (section 5.1)
- Impact of sialorrhoea on quality of life (section 5.2)
- Application of person-centred care approach (section 5.3)

5.1 Current sialorrhoea management practice

An objective of this study was to explore how sialorrhoea is managed within the Irish context in order to recommend improvements to sialorrhoea management.The negative impact of sialorrhoea on quality of life confirms there is a need for evidence based, effective planning of care in relation to sialorrhoea. Moreover, these negative impacts from sialorrhoea necessitate that health care professionals endeavour to maintain quality of life of the study population.

Firstly, findings from the current study revealed some strengths regarding sialorrhoea management in residential care settings. Healthcare professionals are committed to improving and evaluating the care service through their participation in this research study. Furthermore, these healthcare professionals acknowledged their lack of knowledge and resources and indicated that they wanted to professionally develop through training and educational initiatives. Consequently, the potential for awareness and understanding in order to improve quality of life for people with sialorrhoea was acknowledged. Although there is no specific literature regarding training and education needs for healthcare professional in the care of sialorrhoea, there is a general need for training and education which were identified by HIQA (2016), which reported certain lack of appropriate and relevant mandatory training among caring staff in Irish nursing homes. Sage Support & Advocacy for Older People, Ireland (2016) reported the needs for nursing staff and healthcare assistants to have due training in the care of older people. These documents did not specifically identify training and education in the management of sialorrhoea in older adult residential care settings, however, as findings from this study are demonstrating that sialorrhoea is quite a common condition among older adults in residential care settings, these documents should also apply to the care of sialorrhoea.

The literature search for research within an Irish context, revealed only two papers, one of which is a Cochrane review paper regarding sialorrhoea Botulinum Toxin treatment among PD residents (Hill *et al*., 2016), the other is a case report regarding sialorrhoea Botulinum Toxin treatment among individuals with acquired brain injury (Carroll & McGlone, 2016). The literature search results revealed a lack of sialorrhoea management knowledge and resources. There is clear evidence that major gaps exist in relation to psycho-social and medical sialorrhoea management protocol. Currently, there are no nationally agreed guidelines in relation to a structured management approach to sialorrhoea management within the Irish context.

5.1.1 Systematic assessment regarding sialorrhoea

In the general practice of management sialorrhoea, as described in the literature, the first step is to make an assessment in order to evaluate and monitor the effectiveness of any interventions (Fairhurst &Cockerill, 2009; Reddihough *et al*., 2010; Bavikatte *et al*., 2012; Güvenç, 2018). There are a number of objective and subjective assessment tools developed internationally (Thomas–Stonell & Greenberg, 1988; Bothwell *et al*., 2002; Suskind *et al*. , 2002; Lloret et al., 2007; Reid *et al*.,2010; Cazzolli *et al*.,2010; Scheffer *et al*.,2010; Van Hulst *et al*.,2012; McGeachan *et al*., 2015). Evaluating sialorrhoea and its related symptoms would provide a detailed assessment of sialorrhoea related discomfort, and would provide more insight into the relative merits of therapies for sialorrhoea control (McGeachan *et al.,* 2015).

The tools used in the current study were the 'Drooling Severity and Frequency Scale' (DSFS; Thomas–Stonell & Greenberg, 1988), Clinical Sialorrhea Scale (CSS; Lloret et al., 2007) and Clinical Sialorrhoea Scale for MND (CSS-MND; McGeachan *et al*., 2015) which measure the frequency and severity of sialorrhoea and its impact on residents. In this way, the management of sialorrhoea can be tailored according to the findings from these assessment tools, or these tools can be used to measure the effectiveness of management by comparing these assessment results before and after various treatment approaches.

The current study found there were no systematic assessment tools utilised in routine care for residents with sialorrhoea. No MDT members or caregivers reported any assessment framework for sialorrhoea, and no participant had utilised an assessment tool or were aware of the need for these tools. When asked about how sialorrhoea was assessed, the answers from MDT members were 'by visual observation'. Although, the majority of the MDT members agreed with the significance of having assessment tools and expressed their eagerness to improve quality of care, some members did not think there was a need for assessment tools. These members did not think sialorrhoea was a concern because of the low number of older adults with sialorrhoea in their settings. Previous international research has also identified a lack of assessment tools utilised in routine sialorrhoea management. Chaleat-Valayer *et al*. (2016) examined how sialorrhoea was managed with children with CP within the French context and found that sialorrhoea is given insufficient importance and is poorly assessed, leading to insufficient treatment. The evidence of children with CP was used as reference as no research on older adults was found. Chaleat-Valayer *et al*. (2016) also concluded that health professionals' responses highlighted inadequate knowledge regarding assessment tools and available treatments. Similarly, findings from a current study show that none of the MDT participants or caregiver participants were aware of the assessment tools, and the management of sialorrhoea were very limited to mouth wiping and scopoderm patches. Morgante *et al.* (2019) pointed out that despite being associated with poorer quality of life, sialorrhoea is still an under recognised and poorly treated symptom. Findings from the current study also suggest that the prevalence of sialorrhoea is underestimated, and that sialorrhoea severity and frequency along with sialorrhoea impact is probably unknown, as it is not assessed. Thus, the dearth of knowledge in relation to the extent of sialorrhoea and the lack of assessment may lead to poor care and deficits in the management of sialorrhoea (Chaleat-Valayer *et al*., 2016).

5.1.2. MDT involvement in care

In this study, although data from the questionnaire survey identified residents were suffering from moderate to severe sialorrhoea, only 12 (34%) reported team management and findings from the open-ended questions revealed that the teams these participants referred to only included nurses, doctors/GPs, SALTs and healthcare assistants. As discussed in Section 2.8, international literature would suggest that other professions including occupational therapists, dentists, neurologist and physiotherapists should also be involved in the care of sialorrhoea.

After assessment of the presence and the severity of sialorrhoea, different management options can be chosen, which include non-invasive approaches such as behavioural programs, biofeedback, or postural changes. Invasive procedures including medication, radiation, Botulinum toxin injection, and surgery can also be an option in management of sialorrhoea (Dand & Sakel, 2010; Cleary *et al.,* 2011*;* Daniel, 2012; Schroeder *et al*., 2012; Kok *et al*., 2016). Therefore, the involvement of different MDT healthcare members is required in the management of sialorrhoea, and every member of the MDT plays an important role in the care of sialorrhoea (Crysdale *et al*., 2005; Daniel, 2012; Bavikatte *et al*., 2012; Chaleat-Valayer *et al*., 2016; Morgante, *et al*., 2019).

The MDT members in the current study included nursing management staff, nurses, healthcare assistants, consultant/doctor, SALTs OTs, and dietitians. According to what has been described in the literature, the management of sialorrhoea could include nurses, primary care doctors, dentists, ENT doctors, speech and language therapist, and neurologists (Chávez *et al*., 2008; Fairhurst & Cockerill, 2011; McGeachan & McDermott, 2017). Compared with the composition of the MDT from the literature, the Irish MDT generally included in older adult care settings does not include ENT doctors, dentists and neurologists as needed. Findings from this study demonstrated that the level of involvement of the MDT members in the management of sialorrhoea seems to be limited. Although SALTs, OTs and dietitians were involved in the care of older adults with sialorrhoea, their involvement with their care was not directly related to sialorrhoea management. SALTs and OTs might only indirectly help with the issue of sialorrhoea by improving swallowing capacity, and changing body posture or head position (Koheil *et al*., 1987; Nunn, 2000; Van de Burg *et a*l., 2009; Kalf *et al.,* 2011; Bavikatte *et al*, 2012). In the current study, their roles in care of sialorrhoea was not specified and their involvement seemed to be minimum. Some caregivers mentioned that sometimes the use of dentures can cause sialorrhoea, these findings also echo the findings from a study carried out by Binnal *et al*. (2014) which reported that sialorrhoea can cause significant problems with various phases of denture fabrication and also involving wearing dentures. Therefore, dentists should also play a role in care of sialorrhoea as discussed in section 2.8.3. Meningaud *et al*. (2006) also suggested that regular dental examination for tooth decay should be recommended for all residents with sialorrhoea However, a dentist was never mentioned in the focus group discussions and therefore this was not something explored in this study, which demonstrates further MDT involvement is needed in care of sialorrhoea. Daniel (2012) also proposed that the MDT include social workers, because of the medical and physical problems sialorrhoea can present with such as complex social and emotional issues, which can be overwhelming and expose a variety of emotional responses. However, although healthcare professionals from both phases acknowledged the psychological impact of sialorrhoea on residents, there were no mention of the need of social workers in the management of sialorrhoea.

As presented in the literature, the best practice involving sialorrhoea management has been suggested to encompass a multidisciplinary approach with an individualised care plan (Crysdale *et al*., 2006; Reddihough, 2010; Daniel, 2012; Chaleat-Valayer *et al*., 2016; Morgante, *et al*., 2019). Each member of the MDT should make an individual assessment, an analysis of the factors that contribute to sialorrhoea, and identification of strategies to address these factors. Residents with different underlying medical conditions may benefit from a combination of interventions under the management of multiple health care providers with different expertise. Therefore, it is proposed that a hierarchical approach to treatment is taken from least invasive therapies, such as behavioural therapy, to more invasive treatment with medication or surgery (Lal & Hotaling, 2006; de Brujin *et al*., 2017). To follow this approach, the involvement of MDT aims to assess any causative factors which should be corrected to reduce impact on quality of life (Hockstein *et al*., 2004).

The focus of the multidisciplinary management approach is to ensure that the needs of the individual and their caregivers are taken into consideration in order to determine the suitability of the intervention for the resident. The multidisciplinary evaluation and management is time consuming, however, it is a very appropriate way to manage sialorrhoea due to the fact that many residents may have many different medical issues (Crysdale *et al.,* 2005), and all the related causative factors must be recognised and treated or relieved. Participants in phase 1 focus group interviews also supported the recommendation that the MDT management of sialorrhoea is essential to provide more structured care provision with better outcomes.

The MDT approach is important to ensure that all the individual's concerns are addressed and their diverse needs are met. Crysdale *et al.*, (2006) carried out a Canadian quantitative study of neurologically challenged individuals (n= 1487) reported that MDT evaluation with consensus decision-making has worked well with individuals with complex medical conditions. As previously discussed in the literature review (section 2.7) every management technique or approach has its pros and cons, therefore in view of the available evidence and current research finding, a MDT approach with appropriate member involvement is critical to the effective management of sialorrhoea whilst also improving the resident quality of life. Van der Marck *et al*. (2013) carried out a randomized controlled study with 122 PD patients (n=112) and reported positive outcomes with a MDT care approach. Therefore changes are required with regards to Irish care provision for older adults with sialorrhoea in residential care setting. The MDT involvement level within the Irish context should be further developed to meet the diverse needs of the individuals.

5.1.3 Limited management options

Regarding management options, data from both Phase 1 and Phase 2 reported that the application of a scopoderm patch behind the ear seemed to be the only medical treatment used in the study sites. SALTs were involved in assessing the swallowing capacity, but not directly involved in sialorrhoea management. This omission perhaps suggests a gap in sialorrhoea management practice which supports the findings regarding the assessment of sialorrhoea and management plan which were underestimated and under managed. However, this is not unique to the Irish setting, in a UK- based study, Gibbons *et al. (*2019*)* reported that sialorrhoea which impacted on the quality of life of those it affected is an overlooked symptom in PD. Furthermore, Hobson *et al*. (2013) reported evidence from clinical practice which demonstrated that sialorrhoea is sub optimally treated in patients with MND, and that almost half of the treating physicians considered sialorrhoea to be poorly controlled. Within the Irish context, the author was unable to locate any studies carried out to date regarding sialorrhoea management in older adults.

A variety of anticholinergic drugs can be used to manage sialorrhoea including the scopoderm patch. Although studies confirmed the effectiveness of these drugs (Mato Montero *et al.,* 2008; Arbouw *et al.*, 2010; Lloret *et al.*, 2011; Zeller *et al.,* 2012; Odachi *et al.*, 2017; Parr *et al.*, 2018), there is lack of evidence for their long term effects, and there is insufficient data regarding safety (Seppi *et al.*, 2011). The side effects of these drugs have been broadly reported, such as dry mouth, which might be more stressful, as dry mouth may cause poor oral hygiene (Prommer, 2013). Other side effects include vomiting, diarrhea or consitpation, mood swings and sleeping disturbance (Srivanitchapoom *et al.*, 2014; Dias *et al.*, 2016). The most reported side effects of the scopoderm patch by MDT members in this current study were dizziness, and allergic reactions to the patch. Chaleat-Valayer *et al* (2016) found from their study that whilst scopolamine was considered to be less effective than botulinum toxin and to have more side effects, the scopoderm patch is still the first line medication for sialorrhoea management. Findings from Chaleat-Valayer *et al.*, (2016) also confirmed that the scopoderm patch seemed to be the only medication treatment for sialorrhoea and may reflect that there is a limitation of treatment options in sialorrhoea management practice in general.

Therefore, due to the complex health issues with which these older adults in residential care settings present, it seems that non-medication management would be a better choice. There are various non-invasive management approaches reported in the literature, including behavioural therapy carried out by SALTs and wheelchairs designed by OTs that help with residents' back and head support to avoid saliva spilling out the corner of the mouth (Van der Burg *et al.*, 2009; Lamncioni *et al.*, 2011; de Bruijn *et al.,* 2017). However, study findings show that although SALTs and OTs are part of the MDT, they are not particularly involved in the management of sialorrhoea in Ireland. This study identified that the only non-medication management is wiping and oral care either done by residents or their caregivers. It is evident from the current study that additional management options should be explored in the care provided to the older adults with sialorrhoea in residential care settings.

5.1.4 Lack of awareness and training of sialorrhoea management

The results of this study highlighted current sialorrhoea management practice, which revealed obvious gaps in comparison to the findings of best practice from the literature.

Lack of assessment tools and limited management strategies reflected that there is lack of awareness of sialorrhoea, resulting in low priority of its management. These findings agreed with what the older adult participant in phase 1 focus group interview pointed out-'low priority of sialorrhoea'. Phase 2 caregivers also raised the issue of low awareness of sialorrhoea. They stated that sialorrhoea was more common than what people realised, and that sialorrhoea was something they dealt with every day, but there were no talks about it. Although there is no literature directly related to low awareness of sialorrhoea, authors did report that sialorrhoea is under managed (Hobson *et al*., 2013; Gibbons *et al., 2015*; Chaleat-Valayer *et al*., 2016), reflecting low priority and awareness of sialorrhoea. Findings also identified a deficiency of trained staff and resources and lack of coherence of management. This highlights that healthcare education at present does not provide caregivers with the knowledge or skills to facilitate the needs of older adults with sialorrhoea. Some caregivers and MDT members expressed their concern regarding their competence and lack of expertise to manage sialorrhoea and remain passive with respect to resident needs.

In the provision of care to residents with sialorrhoea generally, healthcare professional's clinical knowledge and social knowledge helps to provide residents with the best medical care and social care so as to maintain residents' quality of life. Therefore, healthcare professionals' engagement requires progressive and continuous education by the professional care network (Barello *et al*., 2015). Continuing education is crucial for quality improvement in health care (Gaspard &Yang, 2016). It is necessary for healthcare professionals from across primary, secondary and tertiary care to have specialist education and expertise in the management of sialorrhoea and play key shared roles in the management and support of older adults with sialorrhoea in residential care settings. Healthcare professionals in both phases of the study expressed the need for training and education to upskill the care of sialorrhoea. Current study findings, revealed a clear lack of knowledge regarding sialorrhoea management among healthcare professionals since there is no assessment tool in place and the management strategy is limited. Additionally, there seems to be no recognised training or development programme for healthcare professionals to upskill sialorrhoea management strategies. Therefore, general knowledge of care provision to those residents experiencing sialorrhoea is in urgent need of advancement. Care providers are the ones who provide hands on care to residents, they need to have continuous training with their skills to provide better care, and to improve the level of care of older adults with sialorrhoea by enabling them. Arguably, better primary care provision, collaboration and training are required to sustain a specialist sialorrhoea service.

5.2 Impact of sialorrhoea on quality of life

The main aim of this study sought to evaluate and identify sialorrhoea management protocol in older adult residential care settings within the Irish context, for the purpose of improving quality of life. In order to do so, the first step was to find out how sialorrhoea impacts on residents from both a physical and psychological aspect.

5.2.1 Physical and psychological impact of sialorrhoea

Sialorrhoea often is a complication associated with certain medical conditions. Its impact on residents can sometimes be neglected, however, sialorrhoea can be mentally and socially stressful for residents, impacting on daily living and quality of life. Prior studies carried out by Lloret *et al*. (2007) with 39 PD patients (Mean age 65.4±1.4), Leibner *et al*. (2009) with 59 PD patients (Mean age 69.27±SD5.17) and McGeachan *et al*. (2015) with 50 MND patients (Median age 65) identified that sialorrhoea led to skin lesions, impaired speech and eating, as well as social embarrassment while attending social activities leading to social isolations.

Consistent with the literature, data from the Phase 1 questionnaire with older adults regarding sialorrhoea impact, identified various impacts on residents. Similarly, healthcare professionals from both the focus group interviews and the one-to-one interviews (*n*=28+8) also noted the negative physical and psychological impact of sialorrhoea on residents.

Sialorrhoea can impair eating and speaking (Lloret *et al*., 2007; McGeachan *et al*., 2015), findings from the current study showed that 57.1% of participants suffered different level of impairment of eating and speaking due to sialorrhoea. Some healthcare professionals in both phase 1 and phase 2 also acknowledged that sialorrhoea may affect the functionality of residents, such as speaking and eating.

The constant exposure of the skin to moisture can cause skin lesions and pooled saliva can contribute to the sensation of choking and anxiety (Lloret *et al*., 2007; McGeachan *et al*., 2015; Pellegrini *et al*., 2015; Kok *et al*., 2016; Dias *et al*., 2017; Lawrence & Bateman, 2018; Garuti *et al*., 2019). Skin rash was reported by 37.1% of older adult participants, and coughing or choking were reported by 51.4% of older adult participants in current study. Both Phase 1 and Phase 2 interviews reported that some residents developed a rash and sore around the mouth area which might lead to skin infection and affect skin integrity. Psychologically, sialorrhoea may lead to embarrassment in public and social avoidance due to sialorrhoea (Bavikatte *et al*., 2012; Kok *et al*., 2016). In line with literature, in Phase 1 some older adults reported both social embarrassment and social avoidance, and Healthcare professionals from both phases also acknowledged social embarrassment caused by sialorrhoea.

In summary, these physical and psychosocial complications of sialorrhoea which can range from mild and inconvenient symptoms like skin rash, to severe problems like lung infection or even aspiration pneumonia, can have quite a significant negative impact on quality of life. The results suggest that sialorrhoea is a distressing problem among older adults with neurological medical conditions with impacts on quality of life.

5.2.2 Quality of life

Consideration of quality of life is particularly relevant for older adults in residential care facilities due to their increasing age and levels of dependency (National Council on Ageing and Older People, Ireland, 2000). The population in this study have neurological conditions, such as CVA, dementia and PD and therefore may be considered as one of the most vulnerable groups in society. The findings of the study suggest that sometimes sialorrhoea can be overlooked when other major medical conditions are present also and hence may impact on quality of life. However, this is not something which has been identified elsewhere in the literature. Other physical co-morbidities can detract from the issue of sialorrhoea and this indirectly impacts on quality of life.

Findings from this study clearly revealed the impacts that sialorrhoea has on older adults' quality of life in residential care settings in the South East of Ireland. Twenty one (*n*=21; 66%) out of 32 older adult participants in this study reported some degree of dissatisfaction of life due to sialorrhoea, and a statistical significant result was found between life satisfaction and sialorrhoea impact score following statistical analysis. Healthcare professionals from both phases of the study also acknowledged that resident's quality of life was affected by sialorrhoea. Findings from both quantitative data and qualitative date indicate that the higher the impact of sialorrhoea on individuals, the less satisfaction of life. These data indicate that the quality of life among participants in this study was compromised. Gibbons *et al*. (2019) carried out a study with a group of 41 PD patients in the UK assessing their quality of life and reported that sialorrhoea does have a significant impact on quality of life. Furthermore, Nobrega *et al*. (2008) carried out a pilot study in Brazil with 19 PD patients and suggested that an underestimated consequence of sialorrhoea was silent aspiration which may increase the risk of respiratory infection, and hence reduce quality of life. Apart from these physical consequences of sialorrhoea, the stigma and difficulties with communication, mobility and activities of daily living, indicated greater impairment in quality of life for patients experiencing sialorrhoea compared with patients without sialorrhoea (Ou *et al*., 2015).

Consistent with these findings, healthcare professionals from both phases in the current study reported that the presence of sialorrhoea affected resident's dignity both physically and psychologically, hence reducing quality of life. Findings from phase 1 open-ended questions also confirm the impact on quality of life due to sialorrhoea as participants reported their eating, sleeping and talking were affected and medication for sialorrhoea gave them dry mouth.

Both Phase 1 and Phase 2 presented the concerns of healthcare professionals in relation to how undignified sialorrhoea can be for older adults both physically and psychologically. Although some older adults may not be aware of the existence of sialorrhoea due to their mental capacity, the embarrassment and lack of dignity that the older adults experienced from these study findings clearly indicate there is need to be aware of the impact of sialorrhoea, and hence to maintain and improve quality of life. Older people in residential care settings are more than just residents; they are individuals who deserve to live the remainder of their days with dignity and respect. Therefore, maintaining quality of life of older people in residential care is a central objective and should include the management of sialorrhoea when caring for residents holistically.

Within the Irish context, the Health Act 2007 (Care and Welfare of Residents in Designated Centres for Older People) and National Quality Standards for Residential Settings for Older People in Ireland (HIQA, 2009b, 2016) advocate to ensure rights, protection, health and social care needs along with quality of life of older people. Findings are demonstrating sialorrhoea has an impact on quality of life and therefore, care of sialorrhoea is an element of holistic care as required by these above policy documents.

5.3 Application of person-centred care provision

The theoretical framework that supports this study is the person-centred care framework (the Health Foundation, UK, 2016). Person-centred care is a widely used concept in nursing and health care. The fundamental approach of person-centred care is to provide care that puts the multi-dimensional needs of the resident first, which provides the potential to improve health outcomes and offer physical, psychological and social supports during care of residents.

Person-centred care aims to place the resident at the centre of all care that is carried out, thus, the key to person-centred care is that healthcare professionals work in collaboration with each other and with the residents. The main principles of the person-centred care approach outlined by the Health Foundation, UK (2016) were utilised in this study, to evaluate person-centeredness in care of the older adults in residential care settings.

One of the main aims of this study was to evaluate sialorrhoea management practice within the South East region of Ireland and to subsequently, make recommendations to improve sialorrhoea management. The establishment of the objectives of this study sought to determine the views, challenges and practice needs of older adult in residential care settings in relation to sialorrhoea management. Qualitative findings from Phase 1 and Phase 2 demonstrated the dedication of the healthcare professionals in care of the older adults. However, by comparing the theoretical model with reality, it seems that the current care provision in relation to sialorrhoea was either insufficient at some level or ad hoc, none of the systematic assessment tools were known and available in sialorrhoea management practice, limited management techniques along with a lack of MDT involvement and a lack of resources and knowledge were the main findings from the current study. There is no doubt that caregivers and MDT members are aware of the condition and show their empathy and concerns over resident's dignity, however the lack of integrated care provision and missing elements of the person-centred care approach, such as lack of coordinated and personalised care, was a clear finding in this study.

There is general agreement that the key to effective management of sialorrhoea is via structured integrated care provision (Daniel, 2012; Bavikatte *et al*., 2012; Chaleat-Valayer *et al*., 2016; Morgante, *et al*., 2019). However, findings from this study suggest that there seems to be a lack of structured sialorrhoea management in the provision of person-centred care in residential care settings within the South East region of Ireland.

5.3.1 Provide coordinated care, support, and treatment

As indicated in the literature, sialorrhoea is best managed by a team approach (Daniel *et al*., 2012; Crysdale, 2005; Hockstein *et al*., 2004), however, there are no standardised policies utilised regarding the multidisciplinary or coordinated support offered to residents in this study. This study findings indicate that the management approach to sialorrhoea is mainly a nurse led approach, which indicated lack of collaboration of MDT members.

According to the literature, every member of the MDT should be involved in a systematic assessment of sialorrhoea (Crysdale *et al.,* 2005). A multidisciplinary approach benefits from a holistic assessment from each professional from his or her unique expert perspectives, and thereby provides a comprehensive and holistic view of care. One OT in Phase 1 focus group interviews expressed her concern about not having knowledge regarding sialorrhoea, although she has been working for over 20 years as an OT taking care of older adults in residential care. She was very reluctant to make any comment on the management of sialorrhoea due to lack of expertise. This may indicate that although there is a team available in the residential care settings, there is not expertise or knowledge on sialorrhoea, one director of nursing indicated and discussed in Phase 1 focus group interviews that sialorrhoea is not managed by an MDT approach. Although there is no particular study carried out to examine multidisciplinary management approach, review papers regarding sialorrhoea management all suggest a MDT approach be considered fundamental to ensure that care is consistent and tailored to patients' needs (Fairhurst & Cockerill, 2009; Squires *et al*., 2012; Morgante,*et al*., 2019).

Clear and appropriate communication and interdisciplinary collaboration is critical for delivering quality care for complex patients in health care (Rosenstein & O'Daniel, 2005). In order to address this shortfall in elderly care, there is a need to develop integrated services and pathways for older people with sialorrhoea to meet their complex health and social care needs. The objective is to improve the quality of life for older people suffering from sialorrhoea by providing access to integrated care and support that is planned around their needs and choices, improving their quality of life (Kilpatrick *et al*., 2000; van der Marck *et al*., 2009).

5.3.2 Offer personalised care, support, and treatment

Further findings from this study suggest there is little evidence of personalised care and supports being offered to the older adults in residential care settings. This may be due to lack of awareness and knowledge regarding the issue of sialorrhoea. As discussed previously, research participants from the older adults, the MDT members and caregivers had no knowledge of assessment tools. It is also clear from previous discussion and findings that sialorrhoea is under managed with lack of coordinated care provision, which leads to lack of personalised care provision. In the current study, there is a lack of evidence that personalised sialorrhoea care is offered, the majority of the

MDT and caregivers argued that sialorrhoea is very common, but there was no further discussion or communication regarding sialorrhoea management. Findings from the current study show that in relation to sialorrhoea individual’s personal needs are not addressed or assessed leading to deficit in personalised care provision According to the literature (Crysdale *et al*., 2006; Reddihough, 2010; Silvestre-Rangil *et al*, 2011), after a thorough multidisciplinary assessment, the multidisciplinary team, the resident, and the resident’s family should develop a consensus on appropriate management options which meet the individual’s personal needs. However, this study’s findings reveal that the above mentioned management approach doesn’t happen within the Irish setting, therefore there is an appendant lack of personalised care when it comes to the management of sialorrhoea in older adults.

Some of the focus group participants in this study expressed their appreciation of the study being undertaken and being able to contribute to this study. From their point of view, sialorrhoea is a common issue which they encounter during their daily care of the older adults, however, there is no guidelines directing them what to do and how to do it, in order to offer personalised care to individuals. Therefore, awareness and alignment of goals of sialorrhoea management among multidisciplinary healthcare teams should be raised. An expert team should be constituted, offering personalised care provision, to determine specific, effective management protocol to improve resident’s quality of life and reduce the impact of sialorrhoea.

5.3.3 Enable residents to develop their strengths and abilities

Findings from this study indicate a certain degree of enabling residents, such as letting residents wipe their mouths. However, according to the literature, there are non-invasive management techniques engaging patients in self-management (Van der Burg *et al*., 2009; Lamncioni *et al*., 2011; de Bruijn *et al.,* 2017), and there is no evidence that these management techniques are utilised within the Irish context. This may reveal a lack of knowledge and education to provide residents with information and skills to develop strength and abilities, leading to the need for further training and education. However, there seems to be very limited education and training regarding sialorrhoea management within Irish society. Although, first line healthcare professionals have empathy and compassion to take care of these older adults with sialorrhoea, they would not be able to provide sufficient care. Therefore, MDT members in this study suggested ongoing in service training and education should be in place to support healthcare professionals.

Service providers acknowledged limitations regarding current information provision and training education delivery. It was highlighted by some caregivers in Phase 2 that there are healthcare assistants working in providing care to the elderly with no knowledge about sialorrhoea. In relation to how to facilitate training, they suggested sialorrhoea management should be part of the educational programme for healthcare assistants and should also be ongoing in service training to upskill caregivers in order to provide better care to these older adults and to enable them to develop their strength and abilities. Continuing education is crucial for quality improvement in health care (Gaspard & Yang, 2016). It is necessary for healthcare professionals from across primary, secondary and tertiary care to have specialist education and expertise in the management of sialorrhoea and play key shared roles in the management and support of older adults with sialorrhoea in residential care settings.

5.3.4 Treat people with dignity, compassion, and respect

Residential care has the potential to shape how residents live their lives and who they are (Kane, 2001), and the nature of residential care settings can impact on every aspect of a resident’s life (Kane et al., 2004). In this way, treating residents with dignity, compassion and respect is an important contributor to a resident’s quality of life in residential care settings. Findings show that healthcare professionals from both Phase 1 and 2 of the study endeavoured to treat older adults with dignity, compassion and respect by expressing their concern over older adults’ lack of dignity due to sialorrhoea. They also expressed their challenges in care of older adults with sialorrhoea indicating they are treating older adults with compassion and respect. This study identified two challenges, the first is how to alleviate physical discomfort caused by sialorrhoea, and the other challenge is how to maintain resident’s dignity to reassure them in relation to their emotional needs. However, the questionnaire findings that 7(20%) were not clear if their sialorrhoea was being managed indicated a lack of awareness of the impact sialorrhoea has on older adults.

Overall, the findings indicated that there is no national guideline to direct healthcare professionals, and they were left alone to figure out how to maintain resident's quality of life with no guidance from policy and procedures. This may indicate that to date, not enough attention has been paid by policymakers and regulators to quality of life regarding these older adults with sialorrhoea at both a regional and national level in Ireland.

5.4 Conclusion

This chapter discussed the key findings of the study and compared these findings to those within the literature. The findings were comparable to the literature when available and demonstrated an overall agreement with the results in the study. The study provides valuable information needed when working with older adults with sialorrhoea in residential care settings. Both phase 1 and phase 2 findings revealed the significant impacts of sialorrhoea on older adults. The current study findings also revealed the overall lack of awareness regarding sialorrhoea management, hence the need for improvement in current sialorrhoea management practice in the South East of Ireland was identified. However, because of the limited literature, some of the results have no comparable literature to underpin the findings of this study. Yet, this is not surprising considering the exploratory nature of the study. The two phases of the study, through the mixed method approach identified the gaps in the management of sialorrhoea along with some positive findings regarding an understanding of the need to provide person-centred care and an awareness of resident's dignity. The overall findings from this study indicate that healthcare professionals require further support in order to enhance quality of life and thus, improve person-centred care.

Chapter 6: Conclusion and Recommendations

Introduction

This chapter considers the relevance and implication of the study findings. Section 6.1 discusses the limitations of the study. Following this, section 6.2 highlights the recommendations for practice that result from the study, which includes recommendations for future research, service development, training and education in order to raise awareness and knowledge. The implications of the study are also discussed in relation to the development of clinical practice, theory and policy documents and further research.

6.1Strength & Limitations of the Study

This study was the first study carried out in relation to sialorrhoea in older adult's residential care settings within Irish society, it provided baseline information and insight for healthcare professionals and policy makers, and contributed to nursing and multidisciplinary knowledge by raising awareness of sialorrhoea and identifying gaps in research and practice. This study adopted an exploratory mixed method design, which enhanced the trustworthiness of the research. The mixed methods research in this study also helped to develop a comprehensive and deeper understanding of sialorrhoea by cross-validating and corroborating findings from both the older adults and MDT's perspectives. As a first study within the Irish context, this research highlighted issues regarding sialorrhoea while proposing evidence based guidance in the context of sialorrhoea impact, awareness, assessment and management approaches. This will encourage policy makers, researchers and healthcare professionals to carry out more extensive and intensive research in order to develop sialorrhoea management protocol leading to optimum care and positive outcomes for older adults with sialorrhoea.

However, limitations exist since it is not possible for a single study to capture all that could be discovered or known about a given topic and certainly a study undertaken by a single researcher, within a limited timeframe. This study is no exception. A number of limitations have been identified with this study. Phase 1 represented survey data gathered from 35 older adults in five residential care settings in the South East. This limited geographical location and low number of participants could be considered to have limited the study generalisability, as this data will not be representative of the entire population of older adults with sialorrhoea in residential care in the South East of Ireland. The small sample size in the questionnaire survey in phase 1 may reduce the representativeness of the entire population, and may also affect the reliability of the survey's results because it leads to a higher variability, which may lead to bias. Therefore, the small sample size in this study may undermine the internal and external validity of the study. This was justified by adding an extra phase to further confirm the findings.

Secondly, some older adults with sialorrhoea in residential care settings were not included in this survey for ethical reasons involving informed consent. This applied to both phase 1 and phase 2. It was ethically not possible to survey or interview some from this group as they may not have been able to give informed consent due to their mental capacity. This may mean that some aspects were missed in the study causing certain bias. This purposive sampling relies on the perspective of the researcher and is considered a bias within the study.

Furthermore, generalisation and external validity in qualitative research methods would not be expected from this small scale study. Due to small sample size in phase 1 questionnaire survey, phase 2 was added as retrospective phase, and phase 2 guided interview topics were only reviewed, which may also reduce the validity of the quantitative data. However, a level of rigour was applied to every aspect of this research as discussed in Section 3.7.2.3. Hence, the findings from this study could reflect other older adult residential care settings. However, it is clear that the findings cannot be generalised to the whole population due to purposive sampling.

There are also some methodology limitations of which were previously discussed in the research method chapter. Mixed methods studies are complex to plan and conduct, integrating qualitative and quantitative data during analysis is often a challenge. Given that each method must adhere to its own standards for rigor, ensuring appropriate quality of each component of a mixed methods study can be difficult (Onwuegbuzie et al., 2011).Regarding this study, the concurrent phase 1 involved both quantitative and qualitative data sets with different samples and different sample sizes which can be challenging to merge and also interpret their results in a meaningful way. This is because it can be difficult to compare the results of two analysis using data of different forms, and it may be unclear how to resolve discrepancies that arise while comparing the results. The emergent phase 2 was a sequential explanatory design, as an emergent phase, it may compromise the main research objectives, secondly, the priority of sequential explanatory design is generally given to the quantitative data, and the findings are integrated during the interpretation phase of the study. However in this study, the limitation of phase 1 concurrent data integration as discussed above may reduce the validity of the data collected in this phase.

6.2 Recommendations

The final objective of this study was to make recommendations for the development of sialorrhoea management pracitice in Ireland. This was achieved by undertaking the questionnaire survey with older adults (*n*=35), focus group interviews (*n*=5; 29 participants) with MDT members and older adult and one to one indepth interviews (*n*=8) with caregivers. These different studies were combined together with the available literature to explore potential service improvement and changes that were needed in order to improve care provision from the specific service under study to wider Irish residential care services. Recommendations are made in the following areas and are summarised in table 6.1.

Service development:

- Increasing awareness of sialorrhoea among healthcare professionals to improve resident care.
- Systematic assessment of sialorrhoea, with integrated person-centred care as the goal of the management approach.

- A multidisciplinary team should be involved in the thorough evaluation of sialorrhoea of older people in residential care to reach decisions on the care plan for sialorrhoea management.
- An integrated care plan of sialorrhoea should be in place for each individual who suffers from sialorrhoea and should be reviewed regularly.
- The assessment should pay particular attention to any treatments or programmes of rehabilitation that could improve the person's health status through the alleviation or cure of an illness or condition in order to provide coordinated care of sialorrhoea.
- Further establish networks of shared care between the mulitidisciplinary team members for updated care provision of sialorrhoea.
- SALTs, OTs, Physiotherapists should be more actively engaged in the management of sialorrhoea. Social workers should also engage in the care of older adults with sialorrhoea for socio psychological support as well as support for family members, because sialorrhoea can be quite stressful for many residents and their families.

Education and training:

- Ensure that healthcare professionals nationwide receive up to date training in evidence-based management methods and as a result, older adults in residential care in Ireland will receive equitable and effective health care in relation to sialorrhoea issues.
- Develop national evidence based guidelines to direct the management of sialorrhoea, especially protocols for nurses to follow in everyday care of older adults.
- In relation to how to facilitate training and education, it would be beneficial if sialorrhoea management was part of the educational programme for healthcare assistants and also if ongoing in service training to upskill caregivers was provided.
- Regarding other healthcare professionals, SALTs, OTs and Physiotherapists, training on non-invasive management techniques training would enhance care

and also enable residents to develop their strength and abilities.

Further research:

- More research is needed to demonstrate the benefits, side effects, and cost effectiveness of treatment options in the various conditions causing sialorrhoea in older adults.
- Further research to explore behaviours in older adults when seeking help due to occurrence of sialorrhoea.
- Due to the uniqueness of the older adult population, it is suggested that the management of sialorrhoea should be as non-invasive as possible; further research in sialorrhoea management should be carried out in the following areas: behaviour therapy to aid swallowing frequency by SALTs, customer tailored wheelchair to improve body posture by OTs, and muscle tone training to improve muscle for swallowing capacity by physiotherapists.

Table 6.1 Recommendations:

Service development	Systematic assessment, wider MDT engagement and networking
Education and training	Continuous professional development training, education programmes focus on non-invasive management techniques
Further research	More evidence based research on different management techniques, focus on non-invasive management approach.

6.3 Conclusion

This study explored sialorrhoea management in the older adult residential care settings within the South East region of Ireland. The study was an exploratory mixed study design with purposive sampling technique to examine healthcare professionals' and older adult residents' perceptions of sialorrhoea management within the older adult residential care setting whilst looking at the impact of sialorrhoea and its management approach. It sought to identify effective sialorrhoea management approaches following person-centred care to improve quality of life among these older adults in residential care settings. Relationships were identified between quality of life and impact of sialorrhoea. Gaps of management approach were found indicating the need of more structured care provision complying with the person-centred care approach.

The study highlights the lack of awareness and knowledge of sialorrhoea within the residential care setting. Findings also demonstrated that current practices would benefit from a structured systematic care protocol regarding sialorrhoea, therefore, the person-centred care approach could be augmented by such protocols. Overall, this study demonstrated how sialorrhoea can lower residents' quality of life in the older adult setting. A key finding from the study demonstrated the benefits that integrated care could provide including more focussed person-centred care in the residential home for older adults with sialorrhoea. Therefore, to encourage policy makers, stakeholders and researchers should further investigate effective management protocols in order to provide guidance for healthcare staff on how to manage sialorrhoea, which would then address quality of life in relation to the effects of sialorrhoea in residential care settings. This study findings are significant and useful to inform future strategy on sialorrhoea care provision, with made recommendations made to improve care for older adults with sialorrhoea in residential care setting.

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Appendices

Appendix A. Studies regarding different sialorrhoea management approaches

Non- invasive management of sialorrhoea

Author	Aim	Methods	Participants	Management	key findings
(Marks, et al., 2001) UK	To increase awareness of swallowing saliva in order to provide more control over sialorrhoea, using a behaviour modification approach	Quantitative Randomised controlled Trial questionnaire	28 Participants with PD average age 64.8y	Speech Language therapy intervention Patients were requested to complete monitoring charts for dry swallows for five minutes, three times a day, to increase their awareness of swallowing. A simple brooch style device was used to remind the user to swallow at regular intervals by emitting a beep.	Improvement at one and three months after intervention, significant decrease in sialorrhoea severity in two patients (n=2). The degree of improvement was not fully maintained at three months.
(Johnson *et al.*, 2004) Australia	To determine the effectiveness of an intraoral appliance (the Innsbruck Sensorimotor Activator and Regulator/ISMAR) in improving sialorrhoea in children with CP.	Quantitative Non-randomised trial Questionnaire	18 children with CP Mean age 7.8y	Children were required to wear ISMAR under the instruction of speech pathologist and dentists, the treatment was deemed to begin when children could tolerate the ISMAR for 10 minutes. Once children were able to tolerate for 20 minutes, they were encouraged to wear it overnight.	Only 6 children out of 18 completed the full study (n=6). Many difficulties with compliance encountered during study. For the 6 children who completed the study, sialorrhoea severity scores were improved greatly, but no significant change in sialorrhoea frequency, ISMAR remains a valid option in improving sialorrhoea and merits further study.

(Lancioni *et al.*, 2008) Italy	To determine the effectiveness of using mouth-wiping response instrumental to reduce sialorrhoea via a micro-switch-based programme.	Quantitative Single case experimental observations	2 men with profound intellectual disability Age 21y and 37y	Mini-tilt sensor and radio transmitter hidden. While wiping mouth, the sensor was activated, and radio transmitter emitted signal trigging control system in the room. Prompting and positive reinforcement were key elements in this study.	Significant differences in mouth-drying frequency and chin wetness. However, it did not encompass formal generalization assessment.
*(*Van der Burg *et al*., 2009) The Netherlands	To use Self-management techniques to train individual to control sialorrhoea.	Quantitative Non-randomised trial Questionnaire	9 children with CP, 1 with Worster Drought syndrome Mean age 10.7y	Verbal instruction- 'swallow, check my chin and wipe.' Prompting-positive reinforcement.	Self-management treatment was effective in increasing time of non-sialorrhoea, leading to a positive change in sialorrhoea impact on daily care, social interactions and self-esteem. However, only 3 participants maintained the treatment effects at 6 and 24 weeks follow up. It needs further adaptation to improve efficacy, generalization and maintenance.
(Lancioni *et al*., 2011) Italy	To assess the use of microswitch technology to promote mouth-drying responses to reduce the effect of sialorrhoea	Quantitative single case experimental Observations questionnaire	2 participants intellectual disability Age 46y and 19y	Participants were assigned to wear special napkins that would be activated and produce stimulation when the persons turned and pushed them up against their mouths and chins.	Both participants learned to dry their mouths consistently and reduce their chin wet during the intervention.

(Inal *et al.*, 2017) Turkey	Examine the effect of Functional Chewing on tongue thrust and sialorrhoea in children with CP	Quantitative Randomised control trial questionnaire	32 children with CP age between 4 and 6y	Participants receive functional chewing following instructors from Physiotherapy and Rehabilitation section to restore and improve tongue function, it includes providing sitting posture, positioning food to stimulate tongue movement, chewing tube also to stimulate tongue movement.	Sialorrhoea severity was improved, but no improvement in sialorrhoea frequency. Four participants (n=4) from each group dropped out due to epileptic seizures and botox application, surgical intervention.
(de Bruijn *et al.*, 2017) The Netherland	To explore if the elements of self-management behavioural treatment programme were applicable in an outpatient variant with continued practice at home and at school.	Quantitative, single case experimental	2 participants, one is 7:8y with mild oral motor problem, the other one is 9:10y with CP	First training phase, participants were taught to perform self-management routine, including swallowing, check if their chin was dry, and wiping if their chin as wet. Support from trainer gradually decreased. Second phase, self-instruction using different prompt skills. Third stage, the participants were taught to whisper self-instructions or use internal speech to prompt themselves.	Both participants showed a significant decrease in sialorrhoea severity. Both parents and teachers were satisfied with the effect.
(Marinone *et al.*, 2017) New Zealand	To evaluate the efficacy of Castillo Morales Appliance Therapy in reducing sialorrhoea severity and frequency in children with problematic sialorrhoea.	Quantitative Retrospective Cohort study	53 children with mixed medical conditions. mean age 7.8 y	All participants were treated with Castillo Morales Appliance under the instruction of multidisciplinary saliva control team. This is to achieve a close-mouth posture at rest.	72% (n=38) of the participants had reduction in sialorrhoea severity and frequency. Mean follow up was 51 months, these patients did not require further treatment.

Anticholinergic drugs management of sialorrhoea

Author	Aim	Method	Participants	Management	Key findings
(Mato *et al.*, 2009) UK	To evaluate the efficacy of scopolamine adminstered transdemally for the treatment of sialorrhoea in severely disabled patients.	Quantitative Randomised controlled trial questionnaire	30 participants with different medical conditions: CP, epilespy, autism and Down's syndrome Mean age 30 ±14y	Scopolamine skin patch was placed behind the ear.	Both the severity and frequency of sialorrhoea decreased progressively during treatment. Four (n=4) patients dropped out because of moderatre side effect - one of irritability, one of agitation and two of skin reaction. Three cases (n=3) had minor side effect, one of skin reaction, one of urinary rention, one of mydriasis.
(Parr *et al.*, 2018) UK	To investigate whether hyoscine patch or glycopyrronium liquid is more effective and acceptable to treat sialorrhoea in children with neurodisability.	Quantitive Randomised controlled trial questionnaire	90 children with neurodiability Median age 4y	Children were randomised to receive hyosicne skin patch or glycopyrronium liquid.	Both hyoscine and glycopyrronium are clinically effective in treating sialorrhoea in children with neurodisablity. Hyoscine group, 11 with skin rash, 1 with dry mouth, 1 with pupil dilation, 4 repeatedly pulled off the patch, 3 with unsteady walking, 2 with hyperactivity, 1 with floppiness, 1 with increased seizure activity. Glycopyrronium group, 12 complained of constipation, 7 of excessive drying of respiratory/oral secretion, 3 of skin flushing/dryness.

(Thomsen *et al.*, 2007) Canada	To determine whether sublingual application of ipratropium bromide spray may reduce sialorrhoea without systematic side effects	Quantitative Randomised controlled trial questionnaire	17 patients with PD Mean age 70y	ipratropium bromide spray	Ipratropium bromide spray did not significantly reduce the weight of saliva production, but may have a mild effect on the subjective measure of sialorrhea. No significant adverse side effect
(Arbouw *et al.*, 2010) Netherland	To determine the efficacy and safety of glycopyrrolate in the treatment of sialorrhea in patients with PD.	Quantitative Randomised controlled trial questionnaire	23 patients with PD Mean age 75.4y	oral glycopyrrolate 1 mg, 3 times daily	Nine (n=9) patients (39.1%) with glycopyrrolate had a clinically relevant improvement. There were no significant differences in adverse events between glycopyrrolate and placebo treatment.
(Lloret et al., 2011) Argentina	To explore the safety and anti-sialorrhea efficacy of single doses of intra-oral slow dissolving thin films containing tropicamide (NH004) or placebo.	Quantitative Randomized controlled trial questionnaire	19 non-demented, idiopathic stable or fluctuating PD patients mean age 67±12y	Participants received 3 doses (0.3, 1, 3, mg) of tropicamide and placebo in random order; each dosage regime separated by 7days.	Saliva volume was reduced by 27%, 33% or 20% after tropicamide 0.3, 1 or 3 mg respectively. No adverse events were detected in any of the treatment sequences.

(Odachi *et a*l., 2017) Japan	To determine the efficacy and safety of scopolamine for sialorrhea in ALS	Quantitative Randomised controlled trial questionnaire	20 participants with ALS mean age 71.6y	Scopolamine patches	Patients who received scopolamine showed a greater decrease in volume of daily saliva suction than placebo cases, but the difference was not statistically significant. One developed aspiration pneumonia and discontinued the study. One patient complained of dry mouth, confusion.
(Zeller *et al.*, 2012) USA	To evaluate the efficacy of glycopyrrolate oral solution (1 mg / 5 ml) in managing the problem of sialorrhoea associated with cerebral palsy and other neurologic conditions.	Quantitative Radomised controlled trial questionnaire	38 patients with neurological conditions aged 3–23y	glycopyrrolate (n = 20), 0.02–0.1 mg/kg three times a day	Treatment with glycopyrrolate oral solution significantly improves problem sialorrhoea in children aged 3–16 years with cerebral palsy and other neurologic condition. Side effects were dry mouth, constipation, vomiting, Nasal congestion, Flushing, and Urinary retention.
(Dias *et al.*, 2017) Brazil	To report the effect of sublingual atropine sulfate in treating sialorrhoea in children with cerebral palsy	Quantitative Non-controlled open clinical trial questionnaire	25 participants with CP. mean age 8.6±4.2 y	0.5% sublingual atropine sulfate	There was statistically significant reduction in the DIS score. Side effects were found in four out of the 33 patients who started the study (12.1%) and their respective frequency occurred as follows: fever and flush (n=1); irritability (n=1); flush and irritability (n=1); flush and angioedema (n=1).

Botulinum toxin injection management of sialorrhoea

Author	Aim	Method	Participants	Management	Key findings
(Jackson *et al.*, 2009) USA	To determine Patient perception of benefit of BTx B treatment for sialorrhea in ALS patients	Quantitative Randomised controlled trial questionnaire	20 ALS patients Mean age for BTxB is 67 +/_ 6.8y Placebo mean age 64 +/_ 11.9Y	2500 u of botulinmum type B or placebo was injected into bilateral parotid and submandibular gland	BTx B was well tolerated and appeared to be safe. The most frquent side effect was dy mouth.
(Jongerius *et al.*, 2004) The Netherlands	To investigate the effectivenss of botulimun neurotoxin (BonNT) type A in reducting salivary flow rate in children with CP.	Quantitative Randomised controlled trial questionnaire	45 patients mean age 9.5 +/_3.7y	Single dose BoNT injecton into the submandibular glands, placebo group were treated with scopolamine patches.	Only mild side effects were registered with BoNT treatment; a temporary disturbance in swallowing was reported in 7.6% of patients. BoNT is more favorable when comparing side effects with Scopolamine patch. However, the need for anesthesia is a disadvantage.
(Mancini *et al.*, 2003) Italy	To verify the effectiveness of BoNT type A in treating sialorrhoea in PD patients and to test injection technique	Quantitative Randomised controlled trial questionnaire	20 patients with PD	Patients were injected 450 u of BTX or placebo into the parotids and submadibular glands under ultrasonographic	Injection of BoNT can be considered effective and safe for the treatment of sialorrhoea in PD patients. Patients complained of painful sensation during needle insertion.

				guidance.	
(Lagalla *et al*., 2006) Italy	To investigate the safety and efficacy of botulinum toxin type A treatment to reduce sialorrhea in PD patients.	Quantitative Radomised controlled trial questionnaire	32 PD patients Mean age 69.4+/_ 5.5y Placebo group: 70.5+/_5.5y	Participants were injected either with 50u BoNTX in each parotid gland or placebo without using ultrasound guidance.	Subjects treated with BoNTX experience a reduction in both sialorrhoea frequency and familial and social disability, it is effective and safe. One participant complained of mild transitory swallowing difficulty.
(Reid *et al*., 2008) Australia	To assess the effectiveness of botulinum toxin A injection into the submandibular and parotid glands on children with sialorrhoea, to ascertain the duration of any such effect and the timing of maximal response.	Quantitative Randomised controlled trial questionnaire	48 participants Mean age 11y 4m+/_3y3m	25 units of BoNT-A was injected into the each parotid and submandibular gland. Control group received no treatment	Maximal response was at 1 month with highly significant difference in the mean scores between the groups. This difference remained statistically significant at 6 months. Four children failed to respond to the injections, four had less effective results, and 16 had good results. One reported difficulty swallowing, choking, and deterioration of speech for the first 5 days after the injection. Another developed a severe chest infection on day 5 and a third child had his first seizure 2 days after the injection.

(Martínez-Poles *et al., 2018)* Spain	To determine efficacy of incobotulinum toxin A in treating sialorrhoea in neurological diseases	Quantitative Retrospective and uncontrolled study questionnaire	36 patients with sialorrhoea Mean age 71.1+/_ 17.9y	Average of 43.2 ± 7.6 IU of inco-A (43.2 ± 7.6 mouse LD$_{50}$) was injected into each parotid gland.	As for adverse effects, only one patient (2.8%) reported mild and transitory worsening of previous dysphagia, two months after infiltration with inco-A.
(Tiigimäe-Saar *et al.*, 2018) Estonia	To determine the changes in the oral microflora and saliva in patients with PD treated for sialorrhoea by means of sonography-controlled BNT-A injections into the bilateral parotid and submandibular glands.	Quantatitive Non-randomised control trial questionnaire	25 participants with PD and 13 healthy participants divided into 3 groups. The mean age group1: 71.3y, group2: 71.5y, and group3: 70.y	Group 1 was injected with BNT-A (a total of 250 units Dysport) into the salivary glands to treat hypersalivation. Groups 2 and 3 did not receive any treatment	There were no adverse events, and the treatment was generally well tolerated. There were no complaints of swelling or pain BNT-A injections can effectively treat sialorrhoea while considering the change of oral microflora, and the patients should be under dentists' care more frequently.

Radiotherapy management of sialorrhoea

Author	**Aim**	**Methods**	**Participants**	**Management**	**Key findings**
(Andersen et al., 2001) Sweden	To determine the effectiveness of radiotherapy to parotids and the submandibular glands.	Mixed method Non-randomised Trial Questionnaire interview	18 patients with ALS. Mean age 62.3 Y	Single dose radio-therapy (7 to 7.5 Gray) delivered bilaterally to the larger part of the parotids and the posterior part of the submandibular glands.	Low dosage palliative radiation in a single fraction of 7.0-7.5Gy to the parotid glands is a simple, fast and inexpensive procedure to reduce sialorrhoea in ALS patients. 16 patients experienced sialorrhoea reduction. 1 developed xerostomia and 1 reported no effect.
(Harriman et al., 2001) Canada	To determine the lowest effective dose of radiation to control sialorrhoea.	Quantitative Non-randomised Trial Questionnaire	9 patients with ALS.	First group receive a single dose of 8Gy radiation in one fraction, second group received	8Gy pf radiation was effective, increasing dose did not improve sialorrhoea control. In the first group, 4 patients has significant improvement, in second group, 1 out of 3 patients reported improvement. Side effects included nausea, sore throat and thicker saliva.

				12.5Gy in two fractions.	
(Neppelberg et al., 2007) *Norway*	To investigate the putative effect of palliative single-dose radiotherapy on sialorrhoea in ALS patients.	Quantitative Non-randomised Prospective study Questionnaire	14 patients with ALS. Mean age 68 Y.	Patients received single dose of 7.5 Gy radiation in one fraction.	Single dose radiation therapy reduces sialorrhoea in ALS patients. I patient had slight redness of skin, 1 reported swelling in front of ears, 2 complained about dry mouth.
*(*Stalpers and Moser, 2002*)* The Netherlands	To determine the effectiveness of radiotherapy in reducing sialorrhoea in ALS patients.	Qualitative Non-randomised retro respective study Patients reports	19 patients with ALS.	Patients treated with radiotherapy (prescribed12 Gray in 2 fractions once a week).	14 patients reported some improvement. 4 patients had no improvement, after repeated treatment, 1 had partial improvement. 1 had no improvement after third treatment. Mild side effects include pain and dry mouth.
(Steenbakkes et al., 2018) *The Netherlands*	To assess the effect of salivary glands irradiation on sialorrhoea.	Double blinded Randomised Controlled Trial Questionnaire	31 patients with PD.	11 patients were radiated on the parotid glands, 10 patients on the submandibular glands, 10	Both parotid and submandibular irradiation significantly reduced sialorrhoea. Submandibular irradiation experience sticky saliva.

				were sham irradiated.	
(Cleary et al., 2011) Canada	To determine the effect of radiotherapy on saliva management.	Mixed Method Retrospective Study Questionnaire interview	12 patients with ALS Age range 29-74Y	Patients underwent Radiotherapy	Radiotherapy is effective in reducing sialorrhoea, 10 patients had permanently reduced anti-sialorrhoea drugs. Mild side effects included temporary decrease in taste (n=4), mild nausea (n=4), inflammation (n=4), thrush (n=1) and pain lasting more than 1 week (n=1).

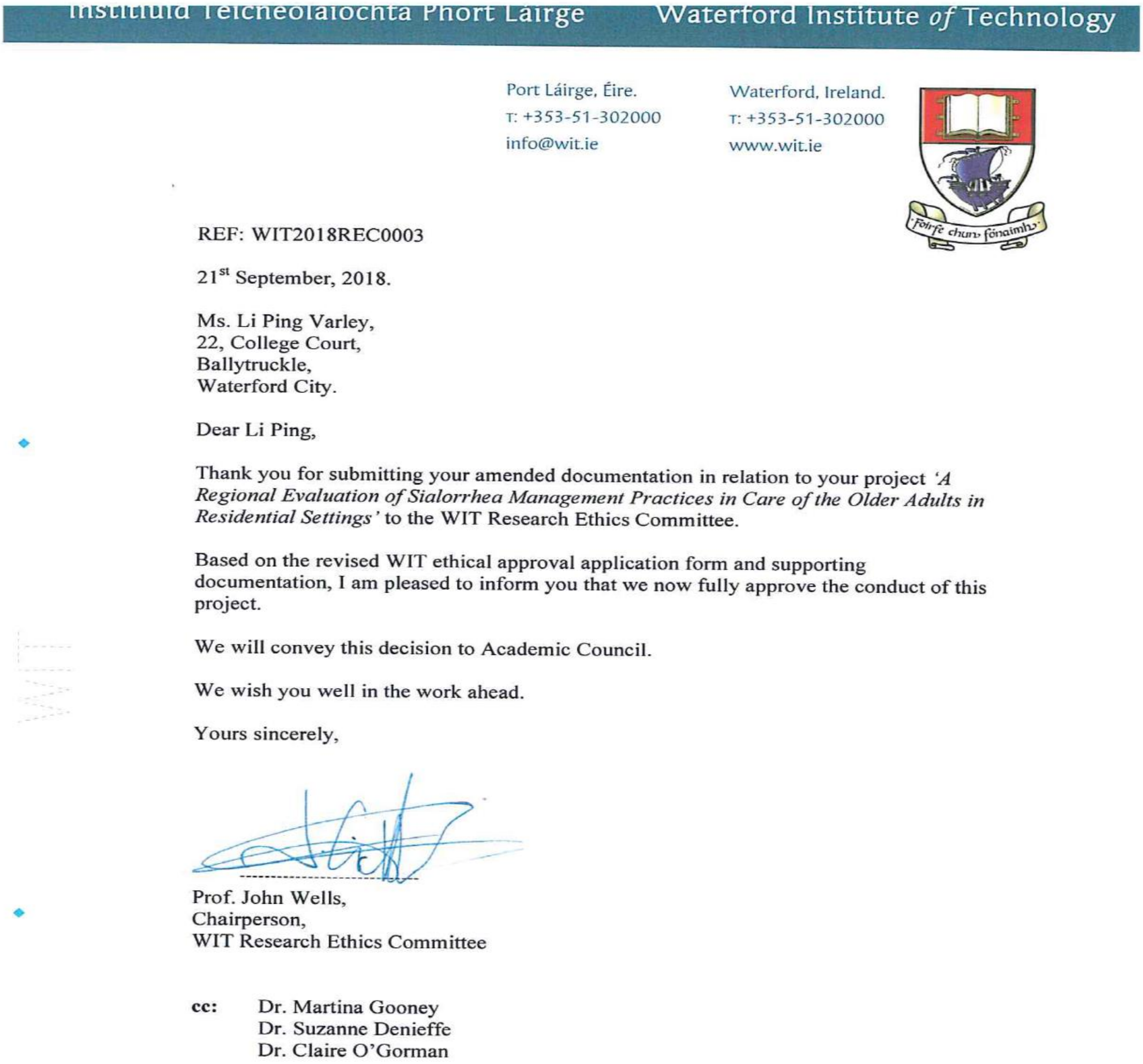
Surgical managment approach

Author	**Aim**	**Method**	**Participants**	**Management**	**Key findings**
*(*Puraviappan *et al.,* 2007) Malaysia	To determine the efficacy of relocating the submanibular duct to treat sialorrhoea in children with CP	Mixed method Descriptive study	8 paricipants mean age 9.75 y	Rolcation of submandibulare duct	All parents were happy with the outcome, this procedure is effective and safe in reducing sialorrhoea in patients with CP. One patient develpoed ranual one month after the surgery. 2 developed postoperative bilateral submandibulare sialoadenitis of 3 days duration.
(Kok *et al.*, 2016) The Netherlands	To evaluate the impact of a reduction in sialorrhoea after bilateral submandibular duct relocation (SMDR) with sublingual gland excision on daily life and care, as well as social and emotional consequences in children and adlolescents wth neurololgical disabilities	Quantitative Prospective cohort study questionnaire	72 participants mean age 15y 2m+/_4y 3m	Submandibular duct relocation	bilateral submandibular duct relocation (SMDR) with sublingual gland excision provides a siginificant reudction in daily care of the cildren suffering from sialorrhoea, caregivers also report positive changes in social interaction and self-estemm. 4 required prolonged intubation due to trasnsient swelling of the floor of the mouth, 3 developed pneumonia, 1 had postoperative unrinary retention. All complications resloved without residual problems and none had problem after surgery which influenced the quality of life at 8 or 32 weeks.

(Stamataki *et al*., 2008) USA	To compare the long term effectiveness of the three surgical techniques and to evaluate long term caregiver satisfaction	Quantitative retrospective cohort study 10 year retrospective chart review and telephone follow-up questionnaire.	33 patients mean age 9.4+/_4.9y	(1) re-routing of the submandibular ducts/excision of the sublingual glands (group 1), (2) excision of the submandibular glands/parotid duct ligation (group 2), and (3) ligation of the parotid and submandibular ducts (group 3).	Six patients were in group 1, 14 in group 2 and 13 patients in group 3. There was no difference in age, sex or severity of sialorrhoea among groups. Mean follow-up was 4.5 years (range 1.1–10 years). Post-operative anti-cholinergic use was most common in group 3 (53%) compared to 21% in group 2 and 33% in group 1. Overall caregiver satisfaction for each group was 83% for group 1, 79% for group 2, and 30% for group 3. Gradual return of sialorrhoea occurred in 8 of 13 (61%) patients in group 3 and resulted in dissatisfied caregivers.
(Stern *et al*., 2002) Israel	To evaluate the safety of bilateral submandibulare gland excision (SGE) with parotid duct ligation (PDL) in the treatment of chronic sialorrhea in children.	Qualititative Case series Telephone interview	93 children with chronic sialorrhoea Age rang 1-10y	bilateral SGE With PDL	There was no operative complications.postoperative complication in 3 patients, 1had a wound hematoma, 1 had significant bilateral swelling,1 had unilateral infection of the parotid gland.72 families were interviewed(follow up 1-10 years), 62(n=62) reported no further sialorrhoea or significant improvement, 7 reported dry mouth, 2 reported in dental caries.

(Khadivi *et al.*, 2013) Iran	To investigate the effect of bilateral submandibular duct rerouting (BSMDR) on sialorrhoea in children with CP.	Quantitative Case series study questionnaire	16 paricipants mean age 12 y	bilateral submandibular duct rerouting	10 days follow up – 87.5% presented overall improvement, 6 months follow up- 81.25% was observed to have overall improvement. 2 cases (n=2) didn't respond to the treatment.18.6% complained of inflammation or infection in the floor of the mouth. 1(6%) had ranual formation.
(Khan *et al.*, 2016) Canada	To report theoutcomes of the 4-duct ligation procedure in pediatric patients and to characterize patient and caregiver satisfaction in a consecutive series	Quantitative retrospective cohort study questionnaire	38 children with neurological impairment median age 11y	underwent a 4-duct salivary gland ligation (parotid and submandibular glands)	Thirteen complications were documented in 12 patients. The most common complications were persistent facial swelling and aspiration pneumonia. Eighty percent (28 of 35) of caregivers reported an improvement in their child's sialorrhoea at 1 month, while 69% (25 of 36) and 71% (24 of 34) stated that there was an improvement at the 1-year follow-up and the most recent follow-up, respectively.

Appendix B: WIT Ethical Approval Letter



Institiúid Teicneolaíochta Phort Láirge Waterford Institute *of* Technology

Port Láirge, Éire.
T: +353-51-302000
info@wit.ie

Waterford, Ireland.
T: +353-51-302000
www.wit.ie

REF: WIT2018REC0003

21st September, 2018.

Ms. Li Ping Varley,
22, College Court,
Ballytruckle,
Waterford City.

Dear Li Ping,

Thank you for submitting your amended documentation in relation to your project *'A Regional Evaluation of Sialorrhea Management Practices in Care of the Older Adults in Residential Settings'* to the WIT Research Ethics Committee.

Based on the revised WIT ethical approval application form and supporting documentation, I am pleased to inform you that we now fully approve the conduct of this project.

We will convey this decision to Academic Council.

We wish you well in the work ahead.

Yours sincerely,

Prof. John Wells,
Chairperson,
WIT Research Ethics Committee

cc: Dr. Martina Gooney
Dr. Suzanne Denieffe
Dr. Claire O'Gorman

Appendix C: Addendum WIT Ethical Approval Letter

Phort Láirge, Éire.
T: +353-51-302000
info@wit.ie

Waterford, Ireland.
T: +353-51-302000
www.wit.ie

REF: WIT2018REC0003

11th June, 2019.

Ms. Li Ping Varley,
22, College Court,
Ballytruckle,
Waterford City.

Dear Li Ping,

Thank you for submitting the addendum in relation to your project *'A Regional Evaluation of Sialorrhea Management Practices in Care of the Older Adults in Residential Settings'* to the WIT Research Ethics Committee.

Based on a review of the WIT ethical approval application form and supporting documentation, I am pleased to inform you that we now fully approve the conduct of this project.

We will convey this decision to Academic Council.

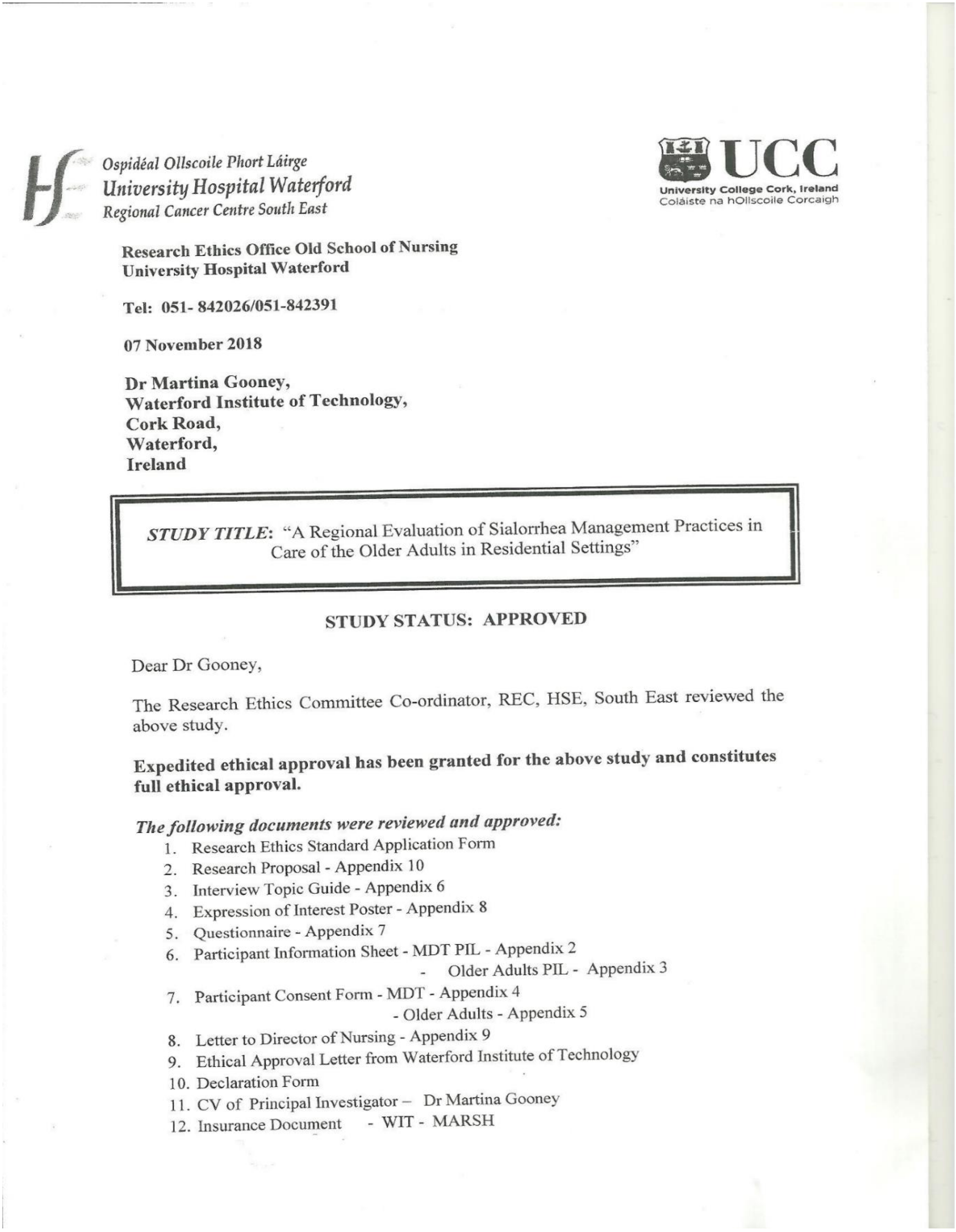
We wish you well in the work ahead.

Yours sincerely,

Prof. John Wells,
Chairperson,
WIT Research Ethics Committee

cc: Dr. Martina Gooney
Dr. Suzanne Denieffe
Dr. Claire O'Gorman

Appendix D: HSE Ethical Approval Letter



Ospidéal Ollscoile Phort Láirge
University Hospital Waterford
Regional Cancer Centre South East

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Research Ethics Office Old School of Nursing
University Hospital Waterford

Tel: 051- 842026/051-842391

07 November 2018

Dr Martina Gooney,
Waterford Institute of Technology,
Cork Road,
Waterford,
Ireland

***STUDY TITLE*:** "A Regional Evaluation of Sialorrhea Management Practices in Care of the Older Adults in Residential Settings"

STUDY STATUS: APPROVED

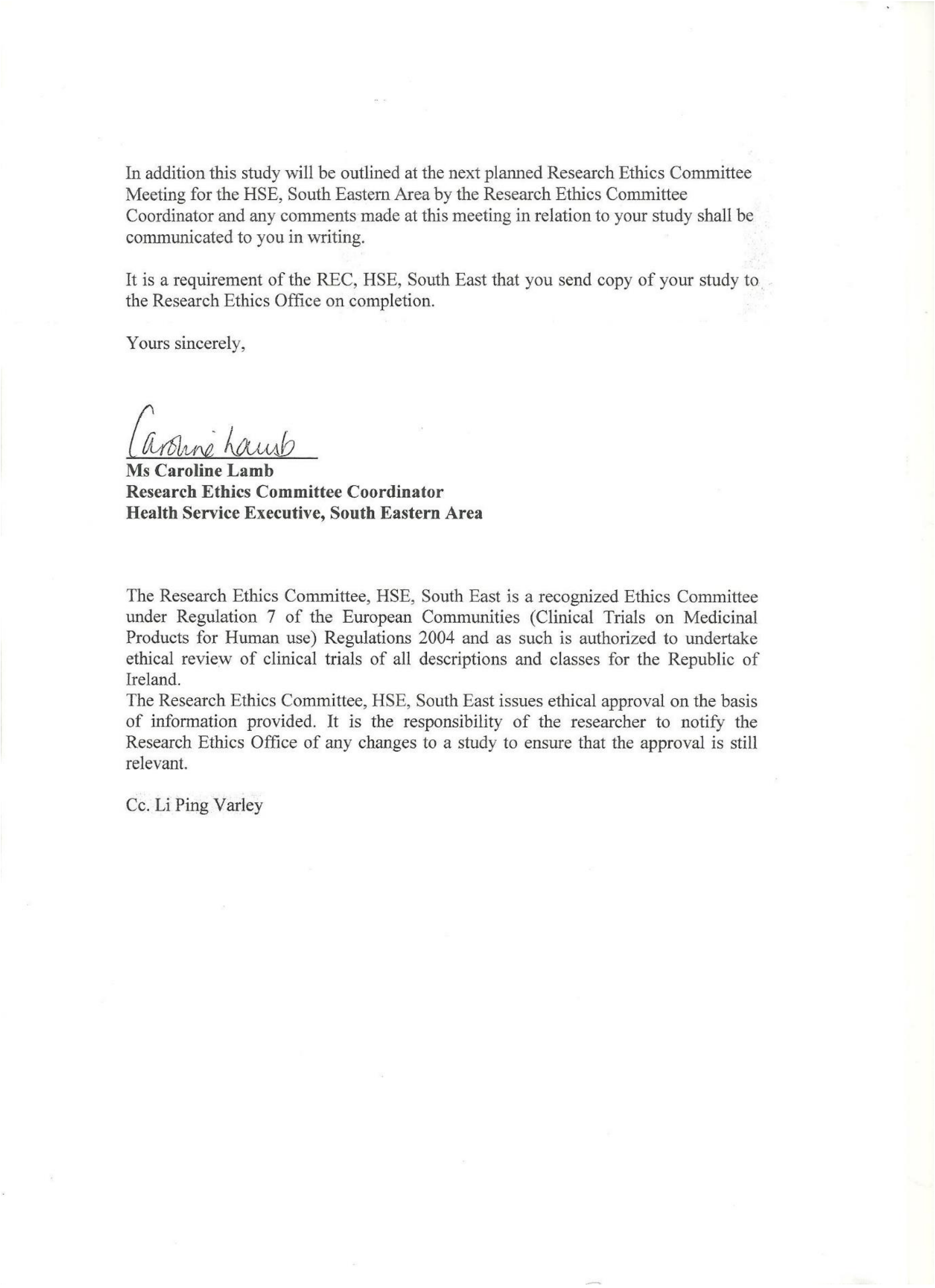
Dear Dr Gooney,

The Research Ethics Committee Co-ordinator, REC, HSE, South East reviewed the above study.

Expedited ethical approval has been granted for the above study and constitutes full ethical approval.

The following documents were reviewed and approved:

1. Research Ethics Standard Application Form
2. Research Proposal - Appendix 10
3. Interview Topic Guide - Appendix 6
4. Expression of Interest Poster - Appendix 8
5. Questionnaire - Appendix 7
6. Participant Information Sheet - MDT PIL - Appendix 2
   - Older Adults PIL - Appendix 3
7. Participant Consent Form - MDT - Appendix 4
   - Older Adults - Appendix 5
8. Letter to Director of Nursing - Appendix 9
9. Ethical Approval Letter from Waterford Institute of Technology
10. Declaration Form
11. CV of Principal Investigator – Dr Martina Gooney
12. Insurance Document - WIT - MARSH



In addition this study will be outlined at the next planned Research Ethics Committee Meeting for the HSE, South Eastern Area by the Research Ethics Committee Coordinator and any comments made at this meeting in relation to your study shall be communicated to you in writing.

It is a requirement of the REC, HSE, South East that you send copy of your study to the Research Ethics Office on completion.

Yours sincerely,

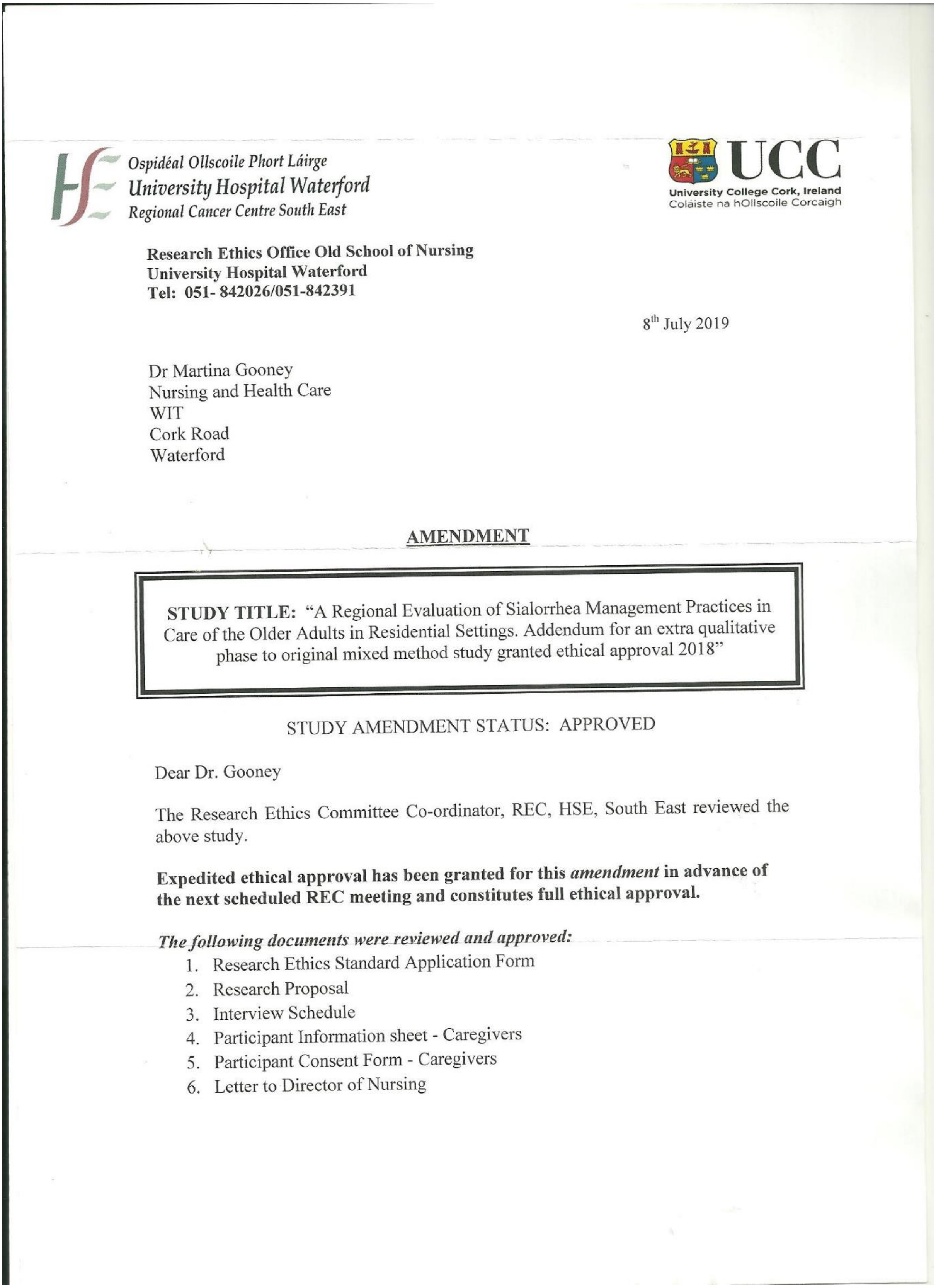
Caroline Lamb

Ms Caroline Lamb
Research Ethics Committee Coordinator
Health Service Executive, South Eastern Area

The Research Ethics Committee, HSE, South East is a recognized Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human use) Regulations 2004 and as such is authorized to undertake ethical review of clinical trials of all descriptions and classes for the Republic of Ireland.
The Research Ethics Committee, HSE, South East issues ethical approval on the basis of information provided. It is the responsibility of the researcher to notify the Research Ethics Office of any changes to a study to ensure that the approval is still relevant.

Cc. Li Ping Varley

Appendix E: Addendum HSE Ethical Approval letter



Ospidéal Ollscoile Phort Láirge
University Hospital Waterford
Regional Cancer Centre South East

UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Research Ethics Office Old School of Nursing
University Hospital Waterford
Tel: 051- 842026/051-842391

8th July 2019

Dr Martina Gooney
Nursing and Health Care
WIT
Cork Road
Waterford

AMENDMENT

STUDY TITLE: "A Regional Evaluation of Sialorrhea Management Practices in Care of the Older Adults in Residential Settings. Addendum for an extra qualitative phase to original mixed method study granted ethical approval 2018"

STUDY AMENDMENT STATUS: APPROVED

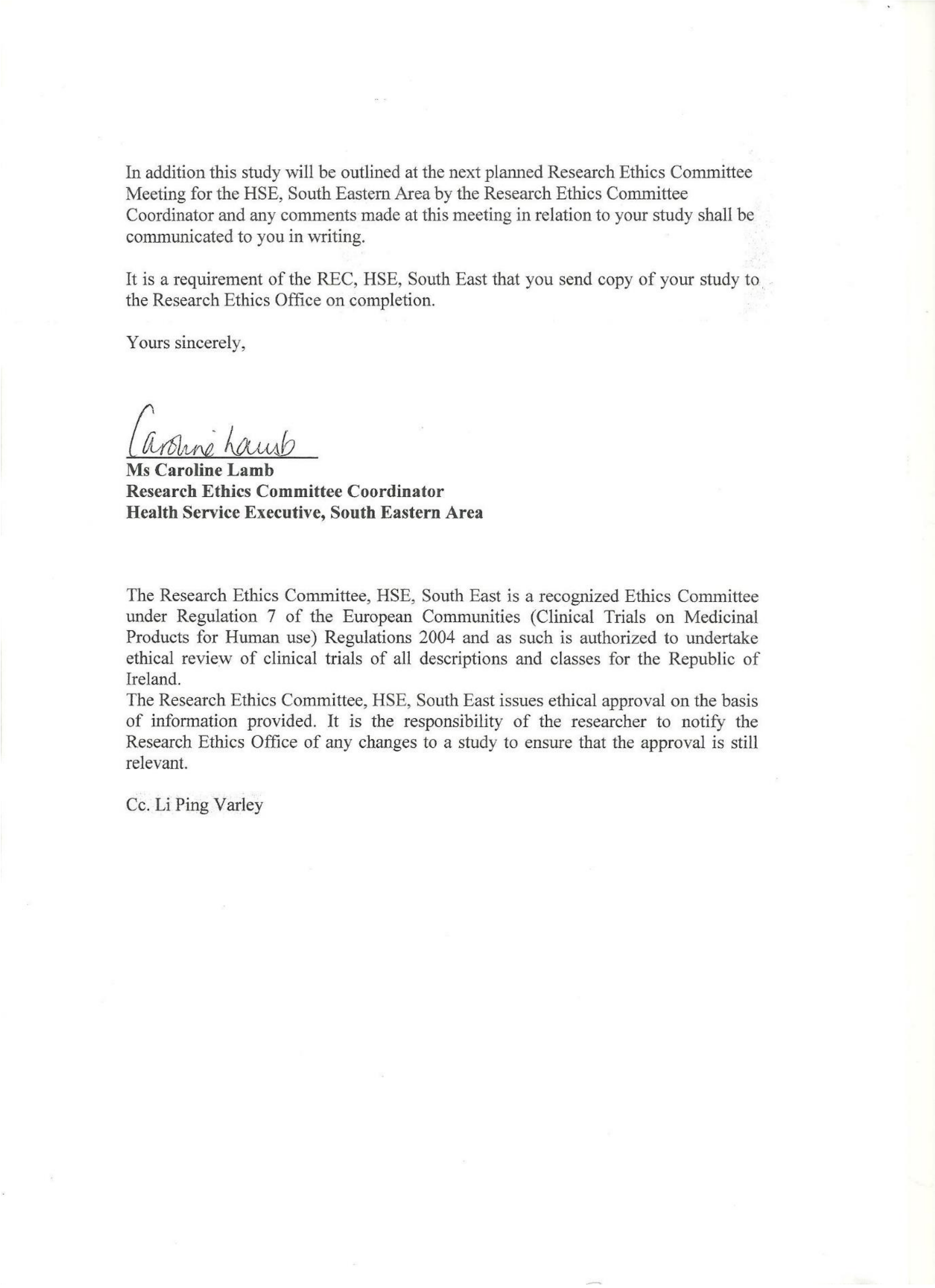
Dear Dr. Gooney

The Research Ethics Committee Co-ordinator, REC, HSE, South East reviewed the above study.

Expedited ethical approval has been granted for this *amendment* in advance of the next scheduled REC meeting and constitutes full ethical approval.

The following documents were reviewed and approved:

1. Research Ethics Standard Application Form
2. Research Proposal
3. Interview Schedule
4. Participant Information sheet - Caregivers
5. Participant Consent Form - Caregivers
6. Letter to Director of Nursing



In addition this study will be outlined at the next planned Research Ethics Committee Meeting for the HSE, South Eastern Area by the Research Ethics Committee Coordinator and any comments made at this meeting in relation to your study shall be communicated to you in writing.

It is a requirement of the REC, HSE, South East that you send copy of your study to the Research Ethics Office on completion.

Yours sincerely,

Caroline Lamb

Ms Caroline Lamb
Research Ethics Committee Coordinator
Health Service Executive, South Eastern Area

The Research Ethics Committee, HSE, South East is a recognized Ethics Committee under Regulation 7 of the European Communities (Clinical Trials on Medicinal Products for Human use) Regulations 2004 and as such is authorized to undertake ethical review of clinical trials of all descriptions and classes for the Republic of Ireland.
The Research Ethics Committee, HSE, South East issues ethical approval on the basis of information provided. It is the responsibility of the researcher to notify the Research Ethics Office of any changes to a study to ensure that the approval is still relevant.

Cc. Li Ping Varley

Appendix F: Multidisciplinary team Information Leaflet

INFORMATION SHEET

Study Title: A Regional Evaluation of Sialorrhoea Management Practices in Care of the Older Adults in Residential Settings

We are inviting members of the multidisciplinary management team in the South East of Ireland residential care settings to take part in a research study to be carried out by Waterford Institute of Technology. Before you decide whether you wish to take part or not, you should read the information provided below carefully, you should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you.

Participation is entirely voluntary, and you can withdraw from the study up to the point of collating of data (three months after the interview) without any reason. This will not affect you in any way in the future, and any related data will be deleted immediately after your withdrawal.

Legal basis for the proposed research:

Waterford Institute of Technology undertakes research as part of its function for the community under its legal status. A full statement of your rights can be found at https://www.wit.ie/about_wit/documents_and_policies/staff_data_protection.

Background: What is this study about?

People with some medical disorders may experience drooling, which causes various complications and affects their quality of life. By interviewing professionals who work in the care of these people, we are hoping to explore current practice in the care of drooling. In turn this will allow us to evaluate practices in order to identify a range of protocols in drooling management to assist care of the target group.

What does the group interview involve?

We ask you questions regarding current practice of drooling management in your work place. This group interview will be audio recorded and all information will be kept strictly confidential. Member check will take place within two weeks after the interview, and consent is sought to use data.

Consenting to participate

If you wish to take part in the study, the principle researcher will contact you again in one week's time after the information session. You will be asked to sign a consent form. It is entirely up to you whether you take part in this interview and to what extent. You also have the right to review and amend your details and can withdraw your consent to use the data up to collating of data (three months after the interview).

Benefits and risks of participation

The information you provide will enable the research team to evaluate current drooling management in older adults' residential settings, and subsequently to make recommendations for healthcare professionals in care of the target group.

In the very unlikely event that the group discussion might upset you, the interview will be stopped and you will be offered to speak to your line manager or director, please see 'https://www.hse.ie/eng/staff/workplacehthwellbng/stfsuprts/eacounsell/' for detail regarding 'The Employee Assistance and Counselling Service (EACS).

Confidentiality

Confidentiality will be respected at all time. All information is kept strictly confidential, the name of your workplace and your own name will never be used in the study. This study is proposed to last for two years; however, data can be stored up to 5 years. The data will be kept in strict confidentiality and will not be passed onto other people or used in any other study. The audio tapes will be destroyed once transcribed and accuracy has been checked. Paper data will be stored in a locked press in WIT office and can only be accessed by the research team subject to the provision of law.

What is the information used for?

The information collected from the study will be used in reports, publications and presentations. All information collected by the researcher will be reported in a way so that you cannot be identified within the research findings. You can request a copy of your part of the discussion at any time.

Any questions or further information?

If you have any questions or concerns, please feel free to contact the research team at:

Li Ping Varley	Dr. Martina Gooney	Dr. Claire O'Gorman
Department of Nursing and Health Care	Department of Nursing and Health Care	Department of Nursing and Heath Care
WIT	WIT	WIT
Tel: 0871530301	Tel: 051-302194	Tel: 051- 305637
email: lvarley@wit.ie	email: mgooney@wit.ie	email: cogorman@wit.ie

EACS contact details: Dorothy McCarthy
Unit 1
University Hospital Waterford
051842786
Dorothy.mccarthy@maila.hse.ie

Data Protection Office: dataprotection@wit.ie **Research Ethics office:** skiely@wit.ie

Thank you

Lipingvarley

Appendix G: Older Adults Information Leaflet

INFORMATION SHEET

Waterford Institute *of* Technology
INSTITIÚID TEICNEOLAÍOCHTA PHORT LÁIRGE

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Study Title: A Regional Evaluation of Sialorrhoea (Drooling) Management Practices in Care of the Older Adults in Residential Settings

You are being invited to take part in a research study to be carried out by Waterford Institute of Technology. Before you decide whether you wish to take part or not, you should read the information below carefully, and you should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you.

Participation is entirely voluntary. You can withdraw from the study any time before processing of the information (three months after the survey) without any reason. This will not affect you in any way in the future, and your information will be deleted immediately after your withdrawal.

Legal basis for the proposed research:

Waterford Institute of Technology undertakes research as part of its function for the community under its legal status. A full statement of your rights can be found at https://www.wit.ie/about_wit/documents_and_policies/staff_data_protection.

Background: What is this study about?

People with some medical disorders may experience drooling, which causes various complications and affects their quality of life. The aim of this study is to measure aspects of drooling and to gather information on the management of drooling in order to improve drooling management.

Why are you invited to participate?

We would like people who are experiencing the issue of drooling to help us in our research study**.**

What does it involve?

Please complete a simple questionnaire indicating the frequency and severity of drooling, as well as how drooling impacts your daily life. All information will be kept strictly confidential.

Consenting to participate

If you wish to take part, you will be invited to an information session. One week later, after you have had time to think about it, you will be asked to sign a consent form. Each time when the researcher team meet with you they will chat with you to make sure you are comfortable and happy to talk with them (checking for verbal consent to continue). You can answer whatever questions you like and you do not need to answer questions you are not happy with. You may also review and change your details, and you can withdraw your consent to use the information before the information is processed (three months after the survey).

Benefits and risks of participation

The information collected from this study will allow us to understand how people are affected by drooling, and how drooling management and treatment helps. The findings of the study may also enable the research team to make recommendations for healthcare professionals in the future. If you feel uncomfortable or upset during the survey, the survey will be stopped immediately, and you will be referred to your key carer, nurse or doctor for support.

Confidentiality

Confidentiality will be respected at all time. All information will be kept strictly confidential, and your own name will never be used in the study. This study is proposed to last for two years; however, your information can be stored up to 5 years. Your information will be kept in strict confidentiality and will not be passed onto other people or used in any other study. Paper information will be stored in a locked press in WIT office. The information can only be accessed by the research team subject to the provision of the law.

What is the information used for?

The information collected from the study will be used in reports, publications and presentations. At no time will your personal information be identifiable.

Any questions or further information?

If you have any questions or concerns, please feel free to contact the research team at:

Li Ping Varley	Dr. Martina Gooney	Dr. Claire O'Gorman
Department of Nursing and Health Care	Department of Nursing and Health Care	Department of Nursing and Heath Care
WIT	WIT	WIT
Tel: 0871530301	Tel: 051-302194	Tel: 051- 305637
email: lvarley@wit.ie	email: mgooney@wit.ie	email: cogorman@wit.ie

Data Protection Officer: dataprotection@wit.ie **Research Ethics officer:** skiely@wit.ie

Thank you

Lipingvarley

Appendix H: Informed Consent Form for Multidisciplinary team

INFORMED CONSENT FROM

A Regional Evaluation of Sialorrhoea (Drooling) Management Practices in Care of the Older Adults in Residential Settings

Statements	Tick if consent is given
I have received information on the study and agree to take part in the study.	
I am satisfied that the benefits and risks of my participation have been explained to me clearly and I am aware of them.	
I understand that the interview will be audio taped.	
I am aware that I have the right to withdraw from the study at any time during the interview and up to correlation of data (three months) after the interview.	
I understand that I can refuse to answer any questions during the interview, and this will not affect me in any way.	
I am aware that all information I give will be in confidence and that my name and other people's names will not be identifiable from the data in any way.	
I understand that topics discussed will be used to help the researcher in her studies and I consent to have my data processed as part of this research study.	
I understand that group interview will have interview facilitator and an observer from the research team.	
The researcher's boundaries on confidentiality have been explained to me. I can contact the Data protection and ethics office if I have any concerns about how my data is used and how I am treated during the study.	
I understand that data collected will be kept only for this study and can be stored up to 5 years after the completion. And under the Freedom of Information legislation I can ask for a copy of our discussion at any time up to 5 years after the interview.	

I have read the information, or it has been read to me. All my questions have been answered to my satisfaction. I consent to take part in this study.

Name in Block Capitals ____________________

Participants Signature ____________________

Date ____________________

To be completed by the Principle Researcher

I, the undersigned, have taken time to fully explain to the above participant the nature and purpose of this study in a way that they could understand. I have explained the potential benefits and risks involved in this study. I have also invited them to ask questions on any aspect of this study that concerned them.

Li Ping Varley

Lipingvarley

Name in Block Capitals Signature Date

Appendix I: Informed Consent Form for older adults

INFORMED CONSENT FORM

Waterford Institute of Technology
INSTITIÚID TEICNEOLAÍOCHTA PHORT LÁIRGE

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Sialorrhoea Management Practices in the Care of the Older Adults in Residential Settings

Statements	Tick if consent is given
I have received information on the study and agree to take part in the study.	
I am satisfied that the benefits and risks of my participation have been explained to me clearly and I am aware of them.	
I am aware that I have the right to withdraw from the study at any time during the survey and up to correlation of data (three months) after the survey.	
I understand that I can refuse to answer any questions in the survey, and this will not affect me in any way.	
I am aware that although I agree to take part in this study now, I have the right to withdraw from the study at any time during the survey and up to correlation of data after the survey.	
I understand that I can refuse to answer any questions from the survey questionnaire, and this will not affect the survey in any way.	
I am aware that all information I give will be in confidence and that my name and other people’s names will not identifiable from the data in any way.	
I understand my survey will be used to help the researcher in her studies, and I consent to have my data processed as part of this research study.	
The researcher’s boundaries on confidentiality have been explained to me. I can contact the Data protection and ethics office if I have any concerns about how my data is used and how I am treated during the study.	
I understand that data collected will be kept only for this study and can be stored up to 5 years after the completion. And under the Freedom of Information legislation I can ask for a copy of our discussion at any time up to 5 years after the interview.	

I have read the information, or it has been read to me. All my questions have been answered to my satisfaction. I consent to take part in this study.

Name in Block Capitals Participants Signature Date

To be completed by the Principle Researcher

I, the undersigned, have taken time to fully explain to the above participant the nature and purpose of this study in a way that they could understand. I have explained the potential benefits and risks involved in this study. I have also invited them to ask questions on any aspect of this study that concerned them.

Li Ping Varley Lipingvarley

Name in Block Capitals Signature Date

Appendix J: MDT Focus Group Interview Topic Guide

Research Study - A Regional Evaluation of Sialorrhoea (Drooling) Management Practices in Care of the Older Adults in Residential Settings

We are interested in some things about you and your work. Please provide some basic information of yourself. The information that you provide will remain strictly confidential.

Job Title					
Education	Diploma	Degree	Postgraduate	Doctor	Others
Working settings (Public/ voluntary/ private)					
Total time in service					
Time in current role					
Job duty					

Questions:

General information about drooling:

1. Tell me about your views on the prevalence of drooling among people in your care?
2. Tell me about your views on causes of drooling?
3. Tell me about your views on drooling impacts on people's quality of life?

Assessment of drooling:

4. Tell me about drooling assessment procedure and who carries out the assessment in your work setting?
5. Tell me about your views on the importance of drooling assessment in the care plan?

Medical treatment of drooling:

6. Tell me about your views on different treatments for drooling?
7. Please tell us what medications are used in the treatment of drooling? ______
8. How effective do you think these medications are? ____
9. Did you notice any side effects of these medications? _____

Non-medical treatment of drooling:

10. Please tell us what non- medical drooling interventions are used in your practice? ____
11. How effective do you think non-medical interventions are? ______

Management of drooling:

12. Tell me about how the effectiveness/adverse effect of drooling intervention strategies are monitored in your workplace? ____
13. Tell me your view about multidisciplinary management of drooling?
14. Tell me your view on external support of drooling management if there is any?
15. Do you think there is any barriers/ challenges to the management of drooling?

Evaluation of current drooling management:

16. Tell me about your general views on current drooling management care provision in Ireland- Opinion of existing treatment and management and potential improvement.
17. Do you have any suggestions/ recommendations from your own experience you would like to make for future development of drooling management?

Finishing the interview

Before finishing the interview, is there anything else you would like to say or add to what has been discussed? Before we conclude this interview, is there something about your experience in this area that we have not yet had a chance to discuss? ____ Thank you.

Appendix K: Survey Questionnaire

Waterford Institute of Technology
INSTITIÚID TEICNEOLAÍOCHTA PHORT LÁIRGE

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

A Regional Evaluation of Sialorrhoea Management Practices in the Care of Older Adults in Residential Settings

Information provided will remain strictly confidential.
Participants may withdraw from the study to the point of collating of data (three months after completion of survey)

Information provided will remain strictly confidential.

I'd like to thank you once again for being willing to participate in my study. As I have mentioned to you before, my study seeks to identify the effective management of drooling practice in order to improve quality of life. We are interested in some things about your health. Please answer all of the questions if possible by circling the number that best applies to you. It will only take you maximum 15 minutes. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Code: I____I

Today's Date (D/M/Y): I____I____I_____I

Below is general information about yourself:

1. Age: _____
2. Sex: M____, F______
3. Main Diagnosis: ______
4. Mobility: 1. Ambulant   2. Non- ambulant 3. Unknown
5. Speech: Verbal / non-verbal
6. Medication treatment for drooling: ________
7. Non-medication treatment for drooling: ______

For the following questions please circle the number that best applies to you

Drooling Frequency and Severity Scale

1. Drooling frequency

- never drools
- occasionally drools (not every day)
- frequently drools (part of every day)
- constantly drools

2. Drooling severity

- dry (never drools)
- mild (only lips wet)
- moderate (wet on lips and chin)
- severe (drool extends to clothes)
- profuse (hands, tray and objects wet)

Revised Sialorrhoea Impact Scale

Please complete the questionnaire with the help of your carer if necessary

A. During the day, when do you feel there is more saliva in your mouth?

0. Never.
1. At meal times.
2. Throughout the day, not related to meals.
3. All the time, even when I am asleep.

B. When you are asleep, how much saliva is there in your mouth?

0. I don’t notice an increase in saliva.
1. I notice increased amounts of saliva in my mouth, but my pillow doesn’t get wet.
2. My pillow gets wet.
3. My pillow and other bedclothes get wet.

C. While you are awake,

0. I don’t drool.
1. Saliva wets my lips.
2. Saliva accumulates on my lips, but I don’t drool.
3. I drool.

D. Are there problems with rashes around the mouth or chin?

0. No
1. Sometimes, but it doesn’t bother me

2. Sometimes and it bothers me
3. Always and it’s very uncomfortable

E. How frequently do you have to wipe your mouth?

0. I don’t need to wipe my mouth
1. Sometimes, but it doesn’t bother me
2. Sometimes and it bothers me
3 I always need to wipe my mouth

F. Does accumulation of saliva in your mouth impair your speech?

0. No.
1. I must swallow frequently to avoid difficulties.
2. I have trouble speaking.
3. I can’t speak at all.

G. Does accumulation of saliva in your mouth impair your eating ability?

0. No.
1. I must swallow frequently to avoid difficulties.
2. I have trouble eating.
3. I can’t eat at all.

H. How many times do you drool during the daytime?

0. Never.
1. Not more than 3 times.
2. Often. I have to carry a handkerchief with me all the time.
3. Permanently.

I. When you go out or on social occasions, does saliva accumulation bother you?

0. No.
1. I notice an accumulation, but it does not bother me.
2. I realize other people notice it, but I can control the situation (for example, with a handkerchief).
3. I have stopped attending social meetings.

J. When you go out or on social occasions, do you notice you are avoided by others?

0. No.
1. I do notice people avoiding me, but it doesn’t bother me
2. I do notice people avoiding me, and it does bother me
3. I am very upset when people avoid me

K. How often does your saliva cause you to cough or choke?

0. Never
1. About once a week saliva goes into the back of my throat and I need to cough.
2. About once a day saliva goes into the back of my throat and I need to cough.
3. Several times a day saliva goes into the back of my throat and I need to cough

L.Is your drooling managed by a multidisciplinary team?

0. No
1. Not sure
2. Sometimes, my GP visits me
3. There is a team looking after my drooling

M. How effective do you think the treatment you receive about your drooling is ?

0. No effect at all
1. It works sometimes
2. It works well
3. It is very effective

N. How satisfied are you with your life overall due to drooling?

0. I am happy
1. I am not entirely happy, but I can manage
2. I am not happy with my life due to drooling
3. Drooling has completely affected the quality of life.

Please answer the following questions:

1. Who is taking care of your drooling?

2. How does drooling affect your daily activities?

3. How is your drooling managed by your care team?

4. Are you aware how your drooling is assessed and how often that your drooling is assessed?

5. Did you notice any side effects of your medication for your drooling treatment if medication is used?

6. Is there anything you want to add about your drooling condition?

Appendix L: Letter to Director of Nursing

Department of Nursing and Health Care
Waterford Institute of Technology
Cork Road, Waterford
email: lvarley@wit.ie, Tel: 087-1530301

08/10/2018

Re: Application for the consent to conduct a Research Study in XX

Research Study: A Regional Evaluation of Sialorrhoea Management Practices in Care of the Older Adults in Residential Settings

To: Director of Nursing in XX

Dear XX

I am currently undertaking an MSc in Sialorrhoea (drooling) Management at Waterford Institute of Technology for which I am required to complete a research project. In doing so, I am hoping to explore views and practices in drooling management from both the multidisciplinary healthcare team and the older adults who experience drooling.
Ethical Approval has been granted by the Waterford Institute of Technology Ethics committee. Ethical Approval has been sought from the Research Ethics Committee of the HSE South-Eastern Area
Pending HSE ethical approval, this study will be carried out under the supervision of Academic Supervisor and Nurse Lecturer, Dr. Martina Gooney of Waterford Institute of Technology. This will be a combination of qualitative and quantitative study design. Subsequently, I intend to recruit the above mentioned two key groups of participants. All data generated will be dealt with anonymously and confidentially.
In this regard, I would like your consent to have access to your site. Please feel me free to contact me at the above address should you have questions regarding this study.

Yours Sincerely

Lipingvarley

Li Ping Varley

Appendix M: One to One Interview Topic Guide

Research Study - A Regional Evaluation of Sialorrhoea (Drooling) Management Practices in Care of the Older Adults in Residential Settings

We are interested in some things about you and your work. Please provide some basic information of yourself. The information that you provide will remain strictly confidential.

Job Title					
Education	Diploma	Degree	Postgraduate	Doctor	Others
Working settings (Public/ voluntary/ private)					
Total time in service					
Time in current role					
Job duty					

Questions:

General information about daily care of patients with drooling

0 = Can you please describe your daily tasks and experience of looking after patients with drooling?

1 = Can you describe a time when you felt there was something more to be done to take care of drooling issues?

2 = Does the above feeling happen on a regular basis? How often?

3 = Tell me about your views on the current care protocol of drooling if there is any.

Questions relating to care of patients

4 = Can you please describe your views on how your patients cope with drooling issues?

5 = Have you noticed that the quality of life of patients are affected by drooling? How?

6 = Tell me about your views on how it affects you as a caregiver while taking care of the patients with drooling.

Questions relating to the main hypotheses of the study

7 = Do you think there is a lack of awareness of problems associated with drooling in the daily care of patients? Why?

8 = Do you think that there should be a structured care pathway in care of people with drooling? Why?

9 = Do you think drooling should be managed by the Multidisciplinary team? Why?

10 = Do you think there should be ongoing training regarding looking after patients with drooling?

Finishing the interview

Before finishing the interview, is there anything else you would like to say or add to what has been discussed? Before we conclude this interview, is there something about your experience in this area that we have not yet had a chance to discuss?

Thank you for your participation in this interview.

Appendix N: Caregiver Information Leaflet

INFORMATION SHEET

Waterford Institute of Technology
INSTITIÚID TEICNEOLAÍOCHTA PHORT LÁIRGE

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Study Title: A Regional Evaluation of Sialorrhoea Management Practices in Care of the Older Adults in Residential Settings

We are inviting members of the multidisciplinary management team in the South East of Ireland residential care settings to take part in a research study to be carried out by Waterford Institute of Technology. Before you decide whether you wish to take part or not, you should read the information provided below carefully, you should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you.

Participation is entirely voluntary, and you can withdraw from the study up to the point of collating of data (three months after the interview) without any reason. This will not affect you in any way in the future, and any related data will be deleted immediately after your withdrawal.

Legal basis for the proposed research:

Waterford Institute of Technology undertakes research as part of its function for the community under its legal status. A full statement of your rights can be found at https://www.wit.ie/about_wit/documents_and_policies/staff_data_protection.

Background: What is this study about?

People with some medical disorders may experience drooling, which causes various complications and affects their quality of life. By interviewing professionals who work in the care of these people, we are hoping to explore current practice in the care of drooling. In turn this will allow us to evaluate practices in order to identify a range of protocols in drooling management to assist care of the target group.

What does the one to one interview involve?

We ask you questions regarding your experience of looking after patients with drooling in your work place. This interview will be audio recorded and all information will be kept strictly confidential. Member check will take place within two weeks after the interview, and consent is sought to use data.

Consenting to participate

If you wish to take part in the study, the principle researcher will contact you again in one week's time after the information session. You will be asked to sign a consent form. It is entirely up to you whether you take part in this interview and to what extent. You also have the right to review and amend your details and can withdraw your consent to use the data up to collating of data (three months after the interview).

Benefits and risks of participation

The information you provide will enable the research team to evaluate current drooling management in older adults' residential settings, and subsequently to make recommendations for healthcare professionals in care of the target group.

In the very unlikely event that the discussion might upset you, the interview will be stopped and you will be offered to speak to your line manager or director, please see 'https://www.hse.ie/eng/staff/workplacehthwellbng/stfsuprts/eacounsell/ for details regarding 'The Employee Assistance and Counselling Service (EACS).

Confidentiality

Confidentiality will be respected at all time. All information is kept strictly confidential, the name of your workplace and your own name will never be used in the study. This study is proposed to last for two years; however, data can be stored up to 5 years. The data will be kept in strict confidentiality and will not be passed onto other people or used in any other study. The audio tapes will be destroyed once transcribed and accuracy has been checked. Paper data will be stored in a locked press in WIT office and can only be accessed by the research team subject to the provision of law.

What is the information used for?

The information collected from the study will be used in reports, publications and presentations. All information collected by the researcher will be reported in a way so that you cannot be identified within the research findings. You can request a copy of your part of the discussion at any time.

Any questions or further information?

If you have any questions or concerns, please feel free to contact the research team at:

Li Ping Varley	Dr. Martina Gooney	Dr. Annette Murphy
Department of Nursing and Health Care	Department of Nursing and Health Care	Department of Nursing and Heath Care
WIT	WIT	WIT
Tel: 0871530301	Tel: 051-302194	Tel: 051- 305637
email: lvarley@wit.ie	email: mgooney@wit.ie	email: acmurphy@wit.ie

EACS contact details: Dorothy McCarthy
Unit 1
University Hospital Waterford
051842786
Dorothy.mccarthy@maila.hse.ie

Data Protection Office: dataprotection@wit.ie **Research Ethics office:** skiely@wit.ie

Thank you

Lipingvarley

Appendix O: Caregiver Informed Consent Form

Informed Consent Form for Caregiver

Waterford Institute *of* Technology
INSTITIÚID TEICNEOLAÍOCHTA PHORT LÁIRGE

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

CONSENT FORM

Study title: **A Regional Evaluation of Sialorrhoea Management Practices in Care of the Older Adults in Residential Settings**

I have read and understood the Information Leaflet about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	***Yes ☐***	***No ☐***
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my future professional practice.	***Yes ☐***	***No ☐***
I am aware of the potential risks, benefits and alternatives of this research study.	***Yes ☐***	***No ☐***
I have been assured that information about me will be kept private and confidential.	***Yes ☐***	***No ☐***
I have been given a copy of the Information Leaflet and this completed consent form for my records.	***Yes ☐***	***No ☐***
I consent to take part in this research study having been fully informed of the risks, benefits and alternatives.	***Yes ☐***	***No ☐***
I give informed explicit consent to have my data processed as part of this research study.	***Yes ☐***	***No ☐***
I consent to be contacted by researchers as part of this research study.	***Yes ☐***	***No ☐***
I understand that the interview will be audio taped.	***Yes ☐***	***No ☐***

FUTURE CONTACT [please choose one or more as you see fit]		
OPTION 1: *I consent to be re-contacted by researchers about possible future research related to the current study for which I may be eligible.*	***Yes ☐***	***No ☐***

OPTION 2: *I consent to be re-contacted by researchers about possible future research unrelated to the current study for which I may be eligible.*	***Yes* ☐**	***No* ☐**

| |

Name (Block Capitals) | Signature | Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above participant the nature and purpose of this study in a way that they could understand. I have explained the risks involved as well as the possible benefits. I have invited them to ask questions on any aspect of the study that concerned them.

| | |

--*Name (Block Capitals) | Qualifications | Signature | Date*

Appendix P Sialorrhea Clinical Scale for PD (SCS-PD) (Perez et al, 2007)

A. During the day, when do you feel there is more saliva in your mouth?

0 = Never.
1 = At meal times.
2 = Throughout the day, not related to meals.
3 = All the time, even when I am asleep.

B. When you are asleep, how much saliva is there in your mouth?

0=I don't notice an increase in saliva.
1=I notice increased amounts of saliva in my mouth, but my pillow doesn't get wet.
2=My pillow gets wet.
3=My pillow and other bedclothes get wet.

C. While you are awake,

0 = I don't drool.
1 = Saliva wets my lips.
2 = Saliva accumulates on my lips, but I don't drool.
3 = I drool.

D. Does accumulation of saliva in your mouth impair your speech?

0 = No.
1 = I must swallow frequently to avoid difficulties.
2 = I have trouble speaking.
3 = I can't speak at all.

E. Does accumulation of saliva in your mouth impair your eating ability?

0 = No.
1 = I must swallow frequently to avoid difficulties.
2 = I have trouble eating.
3 = I can't eat at all.

F. How many times do you drool during the daytime?

0 = Never.
1 = Not more than 3 times.
2 = Often. I have to carry a handkerchief with me all the time.
3 = Permanently.

G. When you go out or on social occasions, does saliva accumulation bother you?

0 = No.
1 = I notice an accumulation, but it does not bother me.
2 = I realize other people notice it, but I can control the situation (for example, with a handkerchief).
3 = I have stopped attending social meetings.

Appendix Q Clinical Saliva Scale for MND (CSS-MND) (McGeachan et al., 2015)

A. During the day, when do you feel there is more saliva in your mouth?

0 = Never.
1 = At meal times.
2 = Throughout the day, not related to meals.
3 = All the time, even when I am asleep.

B. What seems to be the extent of your saliva problem overnight in bed?

0 = I don’t notice an increase in saliva.
1 = I notice increased amounts of saliva in my mouth, but my pillow doesn’t get wet.
2 = My pillow gets wet.
3 = My pillow and other bedclothes get wet.

C. While you are awake,

0 = I don’t drool.
1 = Saliva wets my lips.
2 = Saliva accumulates on my lips, but I don’t drool.
3 = I drool.

D. Does accumulation of saliva in your mouth impair your speech?

0 = No.
1 = I must swallow frequently to avoid difficulties.
2 = I have trouble speaking.
3 = I can’t speak at all.

E. Does accumulation of saliva in your mouth impair your eating ability?

0 = No.
1 = I must swallow frequently to avoid difficulties.
2 = I have trouble eating.
3 = I can’t eat at all.

F. How many times do you drool during the daytime?

0 = Never.
1 = Not more than 3 times.
2 = Often. I have to carry a handkerchief with me all the time.
3 = Permanently.

G. When you go out or on social occasions, does saliva accumulation bother you?

0 = No.
1 = I notice an accumulation, but it does not bother me.
2 = I realize other people notice it, but I can control the situation (for example, with a handkerchief).
3 = I have stopped attending social meetings.

H. How often does your saliva cause you to cough?

0 = Never
1 = About once a week saliva goes into the back of my throat and I need to cough.
2 = About once a day saliva goes into the back of my throat and I need to cough.
3 = Several times a day saliva goes into the back of my throat and I need to cough

I. If you use non-inasive ventilation (NIV), how is excess saliva affecting your use of NIV?

0 = Not at all
1 = The excess saliva makes NIV uncomfortable but I still use it as much as I am supposed to.
2 = My saliva means that I have reduced the amout I use NIV.
3 = I've stopped using NIV because of my salia problem.

Appendix R Drooling Severity and Frequency Scale (DSFS; Thomas-Stonell & Greenberg, 1988)

Drooling Frequency and Severity

1. Drooling frequency

- never drools
- occasionally drools (not every day)
- frequently drools (part of every day)
- constantly drools

2. Drooling severity

- dry (never drools)
- mild (only lips wet)
- moderate (wet on lips and chin)
- severe (drool extends to clothes)
- profuse (hands, tray and objects wet)

Appendix S Study Outputs

Publication

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REVIEW

Journal of Clinical Nursing WILEY

A systematic review of noninvasive and invasive sialorrhoea management

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Funding information This research received funding from Care Collaboration, Nursing and Midwifery Planning and Development Unit, Ireland.

Abstract

Aims and objectives: To review published literature pertaining to the management of sialorrhoea while also highlighting the significance of the multidisciplinary approach.

Background: Sialorrhoea is a common and troublesome problem among certain neurological patients. It is distressing for patients and caregivers, and can be challenging for healthcare professionals. Various sialorrhoea management approaches have been documented. However, there is no clear consensus on best management practices. Therefore, it is necessary to systematically review and synthesise various approaches so as to provide an understanding of the efficacy of management approaches.

Design: Systematic literature review using PRISMA checklist (see Appendix S1).

Method: Five databases (ScienceDirect, Wiley Online Library, CINAHL, Cochrane Library and PubMed) were searched (years 2001–2018) following inclusion criteria. Out of 1,294 identified records, 29 studies met the inclusion criteria.

Results: Various management approaches identified, ranging from noninvasive, such as speech therapy aiming to enhance swallowing behaviour, to invasive treatment including anticholinergic medication, botulinum toxin injection and surgical techniques. However, in the majority of cases, there is no scientific evidence-based management protocol leading to favourable results, and the evidence base for intervention effectiveness remains weak.

Conclusions: The multifactor nature of sialorrhoea and its associated complications presents challenges for the medical care team. None of the management strategies stand alone as the best modality; therefore, it is proposed that management strategies follow a multidisciplinary approach to meet the diverse needs of patients.

Relevance to clinical practice: A comprehensive understanding of different sialorrhoea management approaches will enable healthcare professionals to identify the signs and symptoms regarding sialorrhoea, and to assist in effective management implementation. This will help to improve the management of sialorrhoea, hence, to improve quality of life of patients and provide formative scope to the development of an integrated care pathway.

J Clin Nurs. 2019;00:1–17. wileyonlinelibrary.com/journal/jocn

KEYWORDS

drooling, invasive, management, multidisciplinary, noninvasive, sialorrhoea

1 | INTRODUCTION

Saliva plays a crucial part in maintaining the integrity of the intraoral structures, in digestion and in controlling oral infection. However, numerous physiological and pathological factors can cause variations in salivary flow (Llena-Puy, 2006). Sialorrhoea occurs when saliva spills over the lips, flows outside the mouth, due to an inability to control oral secretions; or weak and infrequent swallowing; or a combination of both, leading to excessive saliva in the oropharynx (Cardoso, 2018). Sialorrhoea is often a problem in patients with different types of neurological disorders, namely neuromuscular diseases, stroke, neurodegenerative disease and dementia (McGeachan & McDermott, 2017). It can be quite a common problem among adults with Parkinson's disease (PD) and amyotrophic lateral sclerosis (ALS) (Mato et al., 2010). Many of the antipsychotics medications can sometimes cause sialorrhoea as well. It is also a frequent issue in children suffering from intellectual disabilities, such as cerebral palsy (CP) and other neurological disabilities (Reid, McCutcheon, Johnson, & Reddihough, 2012).

In general, the reported prevalence of sialorrhoea varies significantly with condition. Approximately 50% of patients with motor neuron disease (MND) or ALS suffer from sialorrhoea, and of those, one in five needs continuous saliva eliminations (Giess et al., 2000; Blackhall, 2012). The prevalence of sialorrhoea in PD patients is estimated between 10%–81% (Nicaretta, Rosso, Maliska, & Costa, 2008; Nicaretta et al., 2015; Damian et al., 2012). Sialorrhoea occurrence among psychiatric patients on clozapine treatment is between 10%–80% (Bird, Smith, & Walton, 2011; Praharaj, Arora, & Gandotra, 2006). Additionally, sialorrhoea among children with CP ranges from 22%–40% (Parkes et al., 2010; Reid et al., 2012). These figures show that sialorrhoea is a significant problem in both children and adults with attendant issues.

There are two broad categories of sialorrhoea: anterior drooling and posterior drooling. Anterior drooling refers to saliva dripping over the lip. Posterior drooling happens when saliva falls posteriorly at the top of the tongue and pools in the hypopharynx, thereby increasing the risk of aspiration (Jongerius et al., 2004; Lawrence & Bateman, 2018). Anterior drooling can lead to peri-oral skin irritation and infection, clothes and furniture soiling and impaired speech capacity, which can lead to social embarrassment and shunning by others (Dias, Fernandes, & Maia Filho, 2017). There is also a physical dimension to drooling. Anterior drooling invariably contributes negatively to appearance which may consequently result in negative perceptions of mental capacity by others. These in turn, overall, impact on confidence and self-esteem, and also reduce opportunities for social inclusion (Kok, Burg, Hulst, Erasmus, & Hoogen, 2016). On the other hand, posterior drooling poses a risk of aspiration and contributes to the sensation of choking and anxiety, which may cause lung injury and respiratory complications if not diagnosed and treated (Dias, Fernandes, & Maia Filho, 2016; Pellegrini, Lunette, Carlo Ferrarese, & Tremolizzo, 2015).

What does this paper contribute to the wider global clinical community?

- Comprehensive synopsis of different management approaches of sialorrhoea provides understanding and awareness of significance of multidisciplinary healthcare approach.
- Multidisciplinary approach allows healthcare professionals to provide comprehensive and optimal care of patients.
- The significance of the multidisciplinary management approach is to ensure a person-centred care pathway in clinical practice.

The chosen sialorrhoea treatment often typically depends on the underlying cause. Nevertheless, due to the complexity of sialorrhoea and its complications, it is very unlikely to have one single completely effective treatment. Ideally, the management approach should be simple, noninvasive, safe and efficient. Therefore, a hierarchy of management approaches starting from the minimum invasive interventions, for example, speech-language therapy, to the more invasive treatments, namely botulinum neurotoxin injection and surgery (de Bruijn, Sohier, & Burg, 2017). Furthermore, people with different attributing factors may benefit from a combination of management approaches. Therefore, the management of drooling may require multiple healthcare providers with different areas of expertise, including nurses, primary care doctors/general practitioners, dentists/orthodontists, ENT (ear, nose, throat) doctors, speech and language therapists, occupational therapists, physiotherapists and neurologists (Fairhurst & Cockerill, 2011; McGeachan & McDermott, 2017; Figure 1). Therefore, it is advisable that sialorrhoea management follows a multidisciplinary approach, on an individualised basis (Crysdale et al., 2006; Reddihough, Erasmus, Johnson, McKellar, & Jongerius, 2010). Adopting a more formulated approach will empower individualised care of patients by implementing specified evidence-based management plans. This approach should lead to more optimistic outcomes, higher satisfaction from patients and greater improvements in quality of life.

Consequently, the initial goal of this literature review is to identify literature containing original data describing various management strategies concerning sialorrhoea. These data are then systematically analysed and synthesised to evaluate the effectiveness

FIGURE 1 Each member of multidisciplinary healthcare professional team plays a role in care of patients with sialorrhoea, and works closely with each other to ensure optimum management approach

TABLE 1 Inclusion and exclusion criteria for literature review

Inclusion criteria	Exclusion criteria
Studies must address the topic of sialorrhoea management, in the area of its effectiveness and side effects of different management strategies RCT trials studies, cohort studies and retrospective studies Papers must be of original design, good quality, and in the English language 2001–2018	Studies that did not meet the inclusion criteria Papers that focused on sialorrhoea assessment, prevalence and validation of assessment tools. Evaluation, reviews, notes, commentary papers, conference papers, books, news

of different management approaches and to inform the identification of optimum approaches to the management of sialorrhoea.

2 | AIMS

To review published literature pertaining to the management of sialorrhoea while also highlighting the significance of the multidisciplinary approach. This paper will also indicate gaps which call for further investigation.

3 | METHODS

Five databases were used in the literature search, namely ScienceDirect, Wiley Online Library, CINAHL, Cochrane Library and PubMed. Search terms included “Drooling” or “Sialorrhea/sialorrhoea” and “management”, “Drooling” or “Sialorrhea/sialorrhoea” and “treatment”, “Drooling” or “Sialorrhea/sialorrhoea” and “intervention”, “Drooling” or “Sialorrhea/sialorrhoea” and “therapy”. The predefined screening criteria (Table 1) are outlined in the PRISMA flow diagram (Figure 2).

A systematic review was conducted to identify relevant literature, and the process of review is recorded in the PRISMA checklist (see Appendix S1). This review includes studies in English published between January 2001–December 2018, as very few papers prior to 2001 were recognised in the primary search. One thousand two hundred and ninety-four identified studies were imported into the Mendeley reference manager. Subsequently, duplicates were removed via Mendeley and refined manually. The screening of identified studies involved three steps: first step, assess the study title; second step, assess the abstracts; and third step, assess and review full text of the studies. One author (LV) assessed paper titles and abstracts for relevance and eligibility, and studies which did not meet

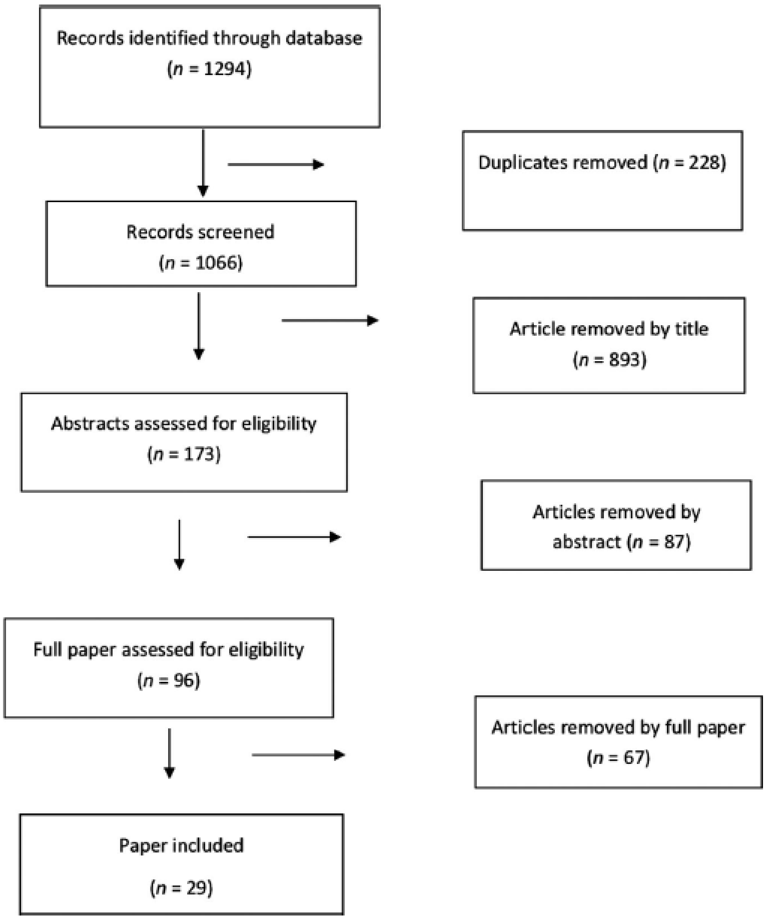

FIGURE 2 PRISMA Flow Diagram (Moher, Liberati, Tetzlaff, & Altman, 2009). Literature search and study identification and screening process

the inclusion criteria were deleted from the list. Subsequently, the remaining papers were read in detail for further screening by two authors (LV and MG) and agreement was reached among reviewers (LV, MG, SD), and analysis was done by the same authors. The final data extracted were read and agreed by all the authors (LV, SD, CO, AM and MG).

3.1 | Quality appraisal

MMAT (Mixed Methods Appraisal Tool) (Pluye et al., 2011) was utilised to assess the quality of the studies. There are 19 methodological quality criteria in MMAT, which can be used for appraising different types of studies. It facilitates the assessment of the following five main categories of studies: qualitative studies, randomised controlled trials (RCT), nonrandomised and descriptive quantitative studies, and mixed methods studies (Pluye et al., 2011). There are four scoring criteria for each type of study. Thus to score it, divide the number of criteria met by four (Vrbnjak, Denieffe, O'Gorman, & Pajnkihar, 2016). Studies with an MMAT study quality appraisal score of <25% (Vrbnjak et al., 2016) were excluded from the review. Mixed Methods Appraisal Tool scores were graded by two reviewers (LV and SD). Data were extracted by two reviewers (LV and MG) and checked by three other reviewers (SD, AM and CO).

4 | RESULTS

One thousand two hundred and ninety-four records were yielded from the search of electronic databases. After duplicates were removed, 1,066 papers were screened by titles and abstracts for relevance and suitability. Subsequently, 970 papers were then removed, 96 (*n* = 96) studies were left to assess their full texts for suitability. After reviewing the full texts, 67 studies were removed. Twenty-nine studies met the inclusion and exclusion criteria for final synthesis. The results of the search are summarised in the PRISMA flow diagram (Figure 2). Mixed Methods Appraisal Tool scores for studies are presented in the tables of management approaches, with all studies scoring at least 50%. Among the 29 studies, twenty-seven are quantitative studies, one is qualitative, and one is a mixed methods study.

TABLE 2 Non-invasive management of sialorrhoea

Author	Aim	Methods	Participants	Management	Key findings	MMAT score
Marks et al. (2001) UK	To increase awareness of swallowing saliva in order to provide more control over drooling, using a behaviour modification approach	Quantitative Randomised controlled Trial Questionnaire	28 Participants with PD Average age 64.8 years	Speech-language therapy intervention Patients were requested to complete monitoring charts for dry swallows for five minutes, three times a day, to increase their awareness of swallowing, a simple brooch style device was used to remind the user to swallow at regular intervals by emitting a beep	Improvement at one and 3 months after intervention, significant decrease in drooling severity in two patients ($n = 2$). The degree of improvement was not fully maintained at 3 months	75%
Johnson et al. (2004) Australia	To determine the effectiveness of an intraoral appliance (the Innsbruck Sensorimotor Activator and Regulator/ISMAR) in improving drooling in children with CP	Quantitative Nonrandomised trial Questionnaire	18 children with CP Mean age 7.8 years	Children were required to wear ISMAR under the instruction of speech pathologists and dentists; the treatment was deemed to begin when children could tolerate the ISMAR for 10 min. Once children were able to tolerate for 20 min, they were encouraged to wear it overnight	Only 6 children out of 18 completed the full study ($n = 6$). Many difficulties with compliance encountered during study. For the 6 children who completed the study, drooling severity scores were improved greatly, but no significant change in drooling frequency. ISMAR remains a valid option in improving drooling and merits further study	50%
Lancioni et al. (2008) Italy	To determine the effectiveness of using mouth-wiping response instrumental to reduce drooling via a microswitch-based programme	Quantitative Single-case experimental Observations	2 men with profound intellectual disability Age 21 years and 37 years	Mini-tilt sensor and radio transmitter hidden. While wiping mouth, the sensor was activated, and radio transmitter emitted signal trigging control system in the room. Prompting and positive reinforcement were key elements in this study	Significant differences in mouth-drying frequency and chin wetness. However, it did not encompass formal generalization assessment	50%
Van der Burg et al. (2009) The Netherlands	To use Self-management techniques to train individual to control drooling	Quantitative Nonrandomised trial Questionnaire	9 children with CP, 1 with Worster-Drought syndrome Mean age 10.7 years	Verbal instruction—"swallow, check my chin and wipe." Prompting-positive reinforcement	Self-management treatment was effective in increasing time of nondrooling, leading to a positive change in drooling impact on daily care, social interactions and self-esteem. However, only 3 participants ($n = 3$) maintained the treatment; effects at 6 and 24 weeks follow-up. Needs further adaptation to improve efficacy, generalization and maintenance	75%

(Continues)

TABLE 2 (Continued)

Author	Aim	Methods	Participants	Management	Key findings	MMAT score
Lancioni et al. (2011) Italy	To assess the use of microswitch technology to promote mouth-drying responses to reduce the effect of drooling	Quantitative single-case experimental Observations Questionnaire	2 participants intellectual disability Age 46 years and 19 years	Participants were assigned to wear special napkins that would be activated and produce stimulation when the persons turned and pushed them up against their mouths and chins	Both participants learned to dry their mouths consistently and reduce their chin wet during the intervention	50%
Inal et al. (2017) Turkey	Examine the effect of Functional Chewing on tongue thrust and drooling in children with CP	Quantitative Randomised control trial questionnaire	32 children with CP Age between 4–6 years	Participants receive functional chewing following instructors from Physiotherapy and Rehabilitation section to restore and improve tongue functions, it includes providing sitting posture, positioning food to stimulate tongue movement, chewing tube also to stimulate tongue movement	Drooling severity was improved, but no improvement in drooling frequency. Four participants ($n = 4$) from each group dropped out due to epileptic seizures and Botox application, surgical intervention	100%
de Bruijn et al. (2017) The Netherland	To explore if the elements of self-management behavioural treatment programme were applicable in an outpatient variant with continued practice at home and at school.	Quantitative, single-case experimental	2 participants, one 7:8 years with mild oral motor problem, the other one 9:10 years with CP	First training phase, participants were taught to perform self-management routine, including swallowing, check if their chin was dry, and wiping if their chin was wet. Support from trainer gradually decreased. Second phase, self-instruction using different prompt skills. Third stage, the participants were taught to whisper self-instructions or use internal speech to prompt themselves	Both participants showed a significant decrease in drooling severity. Both parents and teachers were satisfied with the effect	50%
Marinone et al. (2017) New Zealand	To evaluate the efficacy of Castillo Morales Appliance Therapy in reducing drooling severity and frequency in children with problematic drooling	Quantitative Retrospective Cohort study	53 children with mixed medical conditions. mean age 7.8 years	All participants were treated with Castillo Morales Appliance under the instruction of multidisciplinary saliva control team. This is to achieve a closed-mouth posture at rest	72% ($n = 38$) of the participants had reduction in drooling severity and frequency. Mean follow-up was 51 months; these patients did not require further treatment	100%

TABLE 3 Anticholinergic drugs management of sialorrhoea

Author	Aim	Method	Participants	Management	Key findings	MMAT Score
Mato et al. (2010) UK	To evaluate the efficacy of scopolamine administered transdermally for the treatment of drooling in severely disabled patients	Quantitative Randomised controlled trial Questionnaire	30 participants with different medical conditions: CP, epilepsy, autism and Down's syndrome Mean age 30 ± 14 years	Scopolamine skin patch was placed behind the ear	Both the severity and frequency of drooling decreased progressively during treatment. Four ($n = 4$) patients dropped out because of moderate side effects – one of irritability, one of agitation and two of skin reaction. Three cases ($n = 3$) had minor side effects, one of skin reaction, one of urinary retention, one of mydriasis	75%
Parr et al. (2018) UK	To investigate whether hyoscine patch or glycopyrronium liquid is more effective and acceptable to treat drooling in children with neurodisability	Quantitative Randomised controlled trial Questionnaire	90 children with neurodisability Median age 4 years	Children were randomised to receive hyoscine skin patch or glycopyrronium liquid	Both hyoscine and glycopyrronium are clinically effective in treating drooling in children with neurodisability. Hyoscine group: 11 with skin rash, 1 with dry mouth, 1 with pupil dilation, 4 repeatedly pulled off the patch, 3 with unsteady walking, 2 with hyperactivity, 1 with floppiness, 1 with increased seizure activity Glycopyrronium group: 12 complained of constipation, 7 of excessive drying of respiratory/oral secretion, 3 of skin flushing/dryness	75%
Thomsen et al. (2007) Canada	To determine whether sublingual application of ipratropium bromide spray may reduce drooling without systematic side effects	Quantitative Randomised controlled trial Questionnaire	17 patients with PD Mean age 70 years	ipratropium bromide spray	Ipratropium bromide spray did not significantly reduce the weight of saliva production, but may have a mild effect on the subjective measure of sialorrhea No significant adverse side effect	75%
Arbouw et al. (2010) The Netherlands	To determine the efficacy and safety of glycopyrrolate in the treatment of sialorrhea in patients with PD	Quantitative Randomised controlled trial Questionnaire	23 patients with PD Mean age 75:4 years	Oral glycopyrrolate 1 mg, 3 times daily	Nine ($n = 9$) patients (39.1%) with glycopyrrolate had a clinically relevant improvement. There were no significant differences in adverse events between glycopyrrolate and placebo treatment	75%
Lloret et al. (2011) Argentina	To explore the safety and antisialorrhoea efficacy of single doses of intraoral slow dissolving thin films containing tropicamide (NH004) or placebo	Quantitative Randomized controlled trial Questionnaire	19 nondemented, idiopathic stable or fluctuating PD patients Mean age 67 ± 12 years	Participants received 3 doses (0.3, 1, 3 mg) of tropicamide or a placebo in random order; each dosage regime separated by 7 days	Saliva volume was reduced by 27%, 33% or 20% after tropicamide 0.3, 1 or 3 mg respectively. No adverse events were detected in any of the treatment sequences	100%
Odachi et al. (2017) Japan	To determine the efficacy and safety of scopolamine for sialorrhea in ALS	Quantitative Randomised controlled trial Questionnaire	20 participants with ALS Mean age 71:6 years	Scopolamine patches	Patients who received scopolamine showed a greater decrease in volume of daily saliva suction than placebo cases, but the difference was not statistically significant One developed aspiration pneumonia and discontinued the study. One patient complained of dry mouth, confusion	100%

(Continues)

TABLE 3 (Continued)

Author	Aim	Method	Participants	Management	Key findings	MMAT Score
Zelleret al. (2012) USA	To evaluate the efficacy of glycopyrrolate oral solution (1 mg/5 ml) in managing problem drooling associated with cerebral palsy and other neurologic conditions	Quantitative Randomised controlled trial Questionnaire	38 patients with neurological conditions aged 3–23 years	glycopyrrolate (*n* = 20), 0.02–0.1 mg/kg three times a day	Treatment with glycopyrrolate oral solution significantly improves problem drooling in children aged 3–16 years with cerebral palsy and other neurologic condition. Side effects were dry mouth, constipation, vomiting, Nasal congestion, Flushing, and Urinary retention	100%
Diaset al. (2017) Brazil	To report the effect of sublingual atropine sulphate to treat drooling in children with cerebral palsy	Quantitative Noncontrolled open clinical trial Questionnaire	25 participants with CP Mean age 8.6 ± 4.2 years	0.5% sublingual atropine sulphate	There was statistically significant reduction in the DIS (drooling impact score) score. Side effects were found in four out of the 33 patients who started the study (12.1%) and their respective frequency occurred as follows: fever and flush (*n* = 1); irritability (*n* = 1); flush and irritability (*n* = 1); flush and angioedema (*n* = 1)	75%

The main focus of sialorrhoea management identified is to reduce salivary flow rate, lung infection and other complications, and subsequently to improve social interaction. There are a variety of management approaches ranging from noninvasive, such as speech therapy using different techniques to enhance swallowing behaviour, to invasive treatments including anticholinergic medication, botulinum toxin injections and surgical techniques. However, in the majority of cases, there is no scientific evidence-based management protocol that leads to favourable results, and the evidence base for the efficacy of management approach remains weak.

Each of the Tables 2–5 provides a synopsis of the features of the included studies under different management approaches.

4.1 | Noninvasive management of sialorrhoea (see Table 2)

Generally, noninvasive management is often the first-line therapy choice (McGeachan & Mcdermott, 2017; Pellegrini et al., 2015). Table 2 demonstrates studies that were carried out in different countries, and the studies were carried out under the work of the rehabilitation team, such as speech-language therapists, dentists, and physiotherapists. There are a variety of noninvasive therapies available to manage sialorrhoea. Most studies reviewed focused on a combination of behavioural interventions, for instance, cuing, prompting and reinforcement techniques (Marks, Turner, O'Sullivan, Deighton, & Lees, 2001; Lancioni et al., 2009; Lancioni et al., 2011; de Bruijn et al., 2017; Van der Burg, Didden, Engbers, Jongerius, & Rotteveel, 2009). These behavioural interventions aimed to encourage specific behaviours, for instance, swallowing, self-wiping, head controlling and mouth closing, in order to elicit self-care of sialorrhoea (Van der Burg et al., 2007).

Reinforcement strategy is widely used in studies with children (Marks et al., 2001; lancioni et al., 2011; de Bruijn et al., 2017; Van der Burg et al., 2009). Apart from verbally prompting, studies also used cuing via visual, auditory or vibratory stimuli using technological devices to induce the correct response (Marks et al., 2001; lancioni et al., 2009; lancioni et al., 2011). For example, Marks et al. (2001) used a brooch style device that emitted a beep to remind the wearer to swallow at regular intervals. During the research study carried out by lancioni et al. (2011), when the person pressed the special napkin, assigned them to wear, up against their mouth and chin, the special device in the napkin would activate beeps as stimulation.

Two of the studies used orofacial regulation therapy which employed functional intraoral appliances to increase the capability to stabilise the chin, improve the movement of tongue to improve swallowing and mouth closing and thus to reduce or even eliminate sialorrhoea (Johnson et al., 2004; Marinone, Gaynor, Johnston, & Mahadevan, 2017). There was, however, a high dropout rate in one study due to intolerance of the intraoral appliance. And there was no significant change in the frequency of drooling among those children who completed the study, although the drooling severity scores were improved greatly (Johnson et al., 2004). One study tried to

TABLE 4 Botulinum toxin injection management of sialorrhoea

Author	Aim	Method	Participants	Management	Key findings	MMAT score
Jackson et al. (2009) USA	To determine Patient perception of benefit of BTxB treatment for sialorrhea in ALS patients	Quantitative Randomised controlled trial Questionnaire	20 ALS patients Mean age for BTxB is 67 ± 6:8 years Placebo mean age 64 ± 11:9 years	2500µ of botulinum type B or a placebo was injected into bilateral parotid and submandibular gland	BTxB was well tolerated and appeared to be safe. The most prevalent side effect is dry mouth	75%
Jongerius et al. (2004) The Netherlands	To investigate the effectiveness of botulinum neurotoxin (BonNT) type A in reducting salivary flow rate in children with CP with severe drooling	Quantitative Randomised controlled trial Questionnaire	45 patients Mean age 9.5 ± 3:7 years	Single-dose BoNT injection into the submandibular glands, placebo group were treated with scopolamine patches	Only mild side effects were registered with BoNT treatment; a temporary disturbance in swallowing was reported in 7.6% of patients BoNT has fewer side effects in comparison with Scopolamine patch. However, the need for anaesthesia is a disadvantage	75%
Mancini et al. (2003) Italy	To verify the effectiveness of BoNT type A in treating drooling in PD patients and to test injection technique	Quantitative Randomised controlled trial Questionnaire	20 patients with PD	Patients were injected with 450µ of BTX or a placebo into the parotids and submandibular glands under ultrasonographic guidance	Injection of BoNT can be considered effective and safe for the treatment of drooling PD patients. Patients complained of painful sensation during needle insertion	100%
Lagalla et al. (2006) Italy	To investigate the safety and efficacy of botulinum toxin type A treatment to reduce sialorrhea in PD patients	Quantitative Randomised controlled trial Questionnaire	32 PD patients Mean age 69.4 ± 5.5 years Placebo group: 70.5 ± 5:5 years	Participants were injected 50 u Botox in each parotid gland or placebo without using ultrasound guidance	Subjects treated with BoNTX experience a reduction in both drooling frequency and familial and social disability, it is effective and safe. One participant complained of mild transitory swallowing difficulty	100%
Reidet al. (2008) Australia	To assess the effectiveness of botulinum toxin A injection into the submandibular and parotid glands on children with drooling, to ascertain the duration of any such effect and the timing of maximal response	Quantitative Randomised controlled trial questionnaire	48 participants Mean age 11 years 4 months ± 3 years 3 months	25 units of BoNT-A was injected into the each parotid and submandibular gland. Control group received no treatment	Maximal response was at 1 month with highly significant difference in the mean scores between the groups. This difference remained statistically significant at 6 months. Four children failed to respond to the injections, four had mediocre results, and 16 had good results. One reported difficulty swallowing, choking and deterioration of speech for the first 5 days after the injection. Another developed a severe chest infection on day 5 and a third child had his first seizure 2 days after the injection	75%
Martínez-Poles et al. (2018) Spain	To determine efficacy of incobotulinumtoxin A in treating sialorrhoea in neurological diseases	Quantitative Retrospective and uncontrolled study Questionnaire	36 patients with sialorrhoea Mean age 71.1 ± 17.9 years	Average of 43.2 ± 7.6 IU of incobotulinumtoxin A was injected into each parotid gland	Only one patient (2.8%) reported mild and transitory worsening of previous dysphagia, 2 months after infiltration with inco-A	75%

(Continues)

TABLE 4 (Continued)

Author	Aim	Method	Participants	Management	Key findings	MMAT score
Tiigimäe-Saar et al. (2018) Estonia	To determine the changes in the oral microflora and saliva in patients with PD treated for sialorrhoea by means of sonography-controlled BNT-A injections into the bilateral parotid and submandibular glands	Quantitative Nonrandomised control trial Questionnaire	25 participants with PD and 13 healthy participants divided into 3 groups The mean age Group 1:71:3 years; Group 2:71:5 years and Group 3:70.0 years	Group 1 was injected with BNT-A (a total of 250 units Dysport) into the salivary glands to treat hypersalivation Groups 2 and 3 did not receive any treatment	There were no adverse events, and the treatment was generally well tolerated. There were no complaints of swelling or pain. BNT-A injections can effectively treat sialorrhoea while considering the change of oral microflora, and the patients should be under more-frequent dentists' care	100%

increase tongue movement to reduce sialorrhoea (Inal, Serel Arslan, Demir, Tunca Yilmaz, & Karaduman, 2017); again, however, no improvement was found in the frequency of sialorrhoea.

Each study reviewed aimed to reduce drooling frequency and severity, and each reported a positive result relating to the decrease of sialorrhoea, but none with sufficient long-term effects. All the studies reviewed suggested that these therapies, especially behavioural, self-management therapies, need to be consistent due to the fading of the effect after the treatment (Marks et al., 2001; lancioni et al., 2009; lancioni et al., 2011; de Bruijn et al., 2017; Van der Burg et al., 2009).

Therefore, to conclude, noninvasive management needs more consistent and longitudinal support and is therefore time consuming, which might be a challenge for practice areas. For example, Chaleat-Valayer et al. (2016) conducted a survey of 75 professionals who work with patients who present with sialorrhoea. The results demonstrate that although the majority of professionals prescribe noninvasive management therapies, only 25% prescribe them systematically. Although the eight studies reviewed gave a positive outlook, all authors proposed further studies in relation to this type of management. It seems that the noninvasive approach alone might not be effective in the management of sialorrhoea. Van der Burg, Jongerius, Limbeek, Hulst, and Rotteveel (2006) proposed that noninvasive remedies such as behavioural therapy should be supported by medical interventions.

4.1.1 | Invasive treatments

Invasive procedures are often used to manage sialorrhoea; these include anticholinergic drugs, botulinum toxin injections, radiotherapy and surgery. Although radiotherapy is one of the sialorrhoea management options, only two such related studies were identified. Therefore, there is not enough data to synthesise, and further research into this management approach is required.

4.2 | Anticholinergic drugs (see Table 3)

A variety of anticholinergic drugs are used to manage sialorrhoea, such as hyoscine, scopolamine, glycopyrrolate/glycopyrronium, tropicamide, atropine sulphate and ipratropium bromide (Mato et al., 2010; Parr et al., 2018; Arbouw et al., 2010; Odachi et al., 2017; Lloret, Nano, Carrosella, Gamzu, & Merello, 2011; Zeller, Lee, Cavanaugh, & Davidson, 2012; Dias et al., 2017; Thomsen et al., 2007). All the studies which were reviewed confirmed the effectiveness of systemic anticholinergic drugs (Arbouw et al., 2010; Lloret et al., 2011; Mato et al., 2008; Odachi et al., 2017; Parr et al., 2018; Zeller et al., 2012). However, side effects of these drugs have been broadly reported; approximately 10%–50% of patients suffer from side effects after treatment with anticholinergic drugs (Dias et al., 2017; Mato et al., 2010; Parr et al., 2018; Zeller et al., 2012). These side effects include dry mouth, skin reaction to patches, hyperactivity or change of behaviour, sleep disturbance, constipation and urinary retention (Dias et al., 2016; Mato et al.,

TABLE 5 Surgical management approach

Author	Aim	Method	Participants	Management	Key findings	MMAT score
Puraviappanet al. (2007) Malaysia	To determine the efficacy of relocating the submandibular duct to treat drooling in children with CP	Mixed methods Descriptive study	8 participants Mean age 9:75 years	Relocation of submandibular duct	All parents were happy with the outcome, this procedure is effective and safe in reducing drooling in patients with CP. One patient developed ranula 1 month after the surgery. 2 developed postoperative bilateral submandibular sialoadenitis of 3 days duration	100%
Kok et al. (2016) The Netherlands	To evaluate the impact of a reduction in drooling after bilateral submandibular duct relocation (SMDR) with sublingual gland excision on daily life and care, as well as on social and emotional consequences in children and adolescents	Quantitative Prospective cohort study Questionnaire	72 participants Mean age 15 years 2 months ± 4 years 3 months	Submandibular duct relocation	Bilateral submandibular duct relocation (SMDR) with sublingual gland excision provides a significant reduction in daily care of the children suffering from drooling; caregivers also report positive changes in social interaction and self-esteem. 4 required prolonged intubation due to transient swelling of the floor of the mouth, 3 developed pneumonia, 1 had postoperative urinary retention. All complications resolved without residual problems and none had problem after surgery which influenced the quality of life at 8 or 32 weeks	100%
Stamataki et al. (2008) USA	To compare the long-term effectiveness of the three surgical techniques and to evaluate long-term caregiver satisfaction	Quantitative retrospective cohort study 10-year retrospective chart review and telephone follow-up Questionnaire	33 patients Mean age 9.4 ± 4.9 years	(1) rerouting of the submandibular ducts/excision of the sublingual glands (Group 1), (2) excision of the submandibular glands/parotid duct ligation (Group 2), and (3) ligation of the parotid and submandibular ducts (Group 3)	Six patients were in Group 1, 14 in Group 2 and 13 in Group 3. There were no differences in age, sex or severity of drooling among groups. Mean follow-up was 4.5 years (range 1.1–10 years). Postoperative anticholinergic use was most common in Group 3 (53%) compared to 21% in Group 2 and 33% in Group 1. Overall caregiver satisfaction for each group was 83% for Group 1, 79% for Group 2, and 30% for Group 3. Gradual return of drooling occurred in 8 of 13 (61%) patients in Group 3 and resulted in dissatisfied caregivers	100%

(Continues)

TABLE 5 (Continued)

Author	Aim	Method	Participants	Management	Key findings	MMAT score
Stern et al. (2002) Israel	To evaluate the safety of bilateral submandibular gland excision (SGE) with parotid duct ligation (PDL) in the treatment of chronic sialorrhea in children	Qualitative Case series Telephone interview	93 children with chronic sialorrhoea Age range 1–10 years	Bilateral SGE with PDL	There were no operative complications. Postoperative complications in 3 patients; 1 had a wound haematoma, 1 had significant bilateral swelling, 1 had unilateral infection of the parotid gland. 72 families were interviewed (follow-up 1–10 years), 62(*n* = 62) reported no further drooling or a significant improvement, 7 reported dry mouth, 2 reported dental caries	100%
Khadivi et al. (2013) Iran	To investigate the effect of bilateral submandibular duct rerouting(BSMDR)on drooling in children with CP	Quantitative Case series study Questionnaire	16 participants Mean age 12 years	Bilateral submandibular duct rerouting	10 days of follow-up – 87.5% presented overall improvement, 6 months of follow-up–81.25% were observed to have overall improvement. 2 cases (*n* = 2) did not respond to the treatment. 18.6% complained of inflammation or infection in the floor of the mouth. 1(6%) had ranula formation	50%
Khan et al. (2016) Canada	To report the outcomes of the 4-duct ligation procedure in paediatric patients and to characterize patient and caregiver satisfaction in a consecutive series	Quantitative retrospective cohort study Questionnaire	38 children with neurological impairment Median age 11 years	Underwent a 4-duct salivary gland ligation (parotid and submandibular glands)	Thirteen complications were documented in 12 patients. The most common complications were persistent facial swelling and aspiration pneumonia. Eighty per cent (28 of 35) of caregivers reported an improvement in their child's drooling at 1 month, while 69% (25 of 36) and 71% (24 of 34) stated that there was an improvement at the 1-year follow-up and the most recent follow-up, respectively	50%

2010; Odachi et al., 2017; Parr et al., 2018; Zeller et al., 2012). Among children, some of these side effects also included pupil dilatation (Mato et al., 2008; Odachi et al., 2017; Parr et al., 2018). Some children had to discontinue their treatment with hyoscine patches due to skin reactions to the patch adhesive (Mato et al., 2010; Parr et al., 2018). Adult groups did not report any skin reactions to hyoscine patches (Odachi et al., 2017). No significant side effects from anticholinergic drugs were reported in three out of the four adult studies reviewed (Arbouw et al., 2010; Lloret et al., 2011; Thomsen et al., 2007). One study of the adult group reported dry mouth and confusion (Odachi et al., 2017). Overall, no significant improvement in sialorrhoea was reported compared with the placebo group in older adult patients (Arbouw et al., 2010; Lloret et al., 2011; Odachi et al., 2017). Therefore, further investigation is required to identify an effective option for sialorrhoea management with less side effects.

4.3 | Botulinum toxin injection (see Table 4)

Both botulinum toxins (BoNT) A and B are used for the management of sialorrhoea, and they have shown fewer side effects than anticholinergic medication while also decreasing aspiration pneumonia risk in people with neurological diseases (Faria, Harb, Hilton, Yacobucci, & Pizzuto, 2015). Studies show that botulinum injections are tolerable and effective in the management of sialorrhoea (Jackson et al., 2009; Jongerius et al., 2004; Lagalla, Millevolte, Capecci, Provinciali, & Ceravolo, 2006; Mancini et al., 2003; Martínez-Poles et al., 2018; Reid, Johnstone, Westbury, Rawicki, & Reddihough, 2008; Tiigimäe-Saar, Tamme, Rosenthal, Kadastik-Eerme, & Taba, 2018). However, BoNT does have some side effects which relate to trauma at the injection site as well as adverse effects associated with the botulinum toxin, such as dry mouth, thickened bronchial secretion and viscous saliva, and difficulty chewing (Jackson et al., 2009; Jongerius et al., 2004; Lagalla et al., 2006; Mancini et al., 2003; Martínez-Poles et al., 2018; Reid et al., 2008). Trauma at the injection site can cause adverse effects such as soreness, haematoma, bleeding in the mouth and swollen salivary gland leading to difficulty in swallowing, and it might also cause facial nerve trauma when the injection is performed in the parotid gland (Reddihough et al., 2010). One study result did not show any adverse effect; however, the study recommended patients should be under a dentist's care more frequently due to the change in oral microflora because of the injection (Tiigimäe-Saar et al., 2018).

Although studies confirm BoNT's effectiveness, the maximal response was seen at 1 month and its effect only lasted for approximately 3–6 months (Reid et al., 2008), and it therefore requires administration on a recurrent basis. The repeat injection may lead to antibody formation and fading efficacy (Moller et al., 2015), and the drooling also reverts slowly as the toxin effect wears off (Intiso & Basciani, 2012). Another side effect, although very rare, is that it can sometimes cause dysphagia (Layton, 2014). BoNT injections provide only temporary improvement from sialorrhoea; therefore, recurrent injections are less likely to be a permanent solution.

4.4 | Surgery (see Table 5)

Surgery is usually a last resort, and patients undergo surgery following continued symptoms of profuse, persistent anterior drooling even after the maximal conservative or pharmacological treatments (Lawrence & Bateman, 2018). The aim of surgical approaches is to either decrease or remove stimulation from the nerves to the salivary glands. The surgery includes rerouting or blocking the flow of saliva by inducing atrophy of the glands via ligation, or stopping saliva production by removing the salivary glands (Osorio, Moreira-Pinto, Oliveira, Ferreira-de-Sousa, & Cidade-Rodrigues, 2009; Reed, Mans, & Brietzke, 2009). It seems that surgeries are generally carried out on children with CP (Khadivi et al., 2013; Khan et al., 2016; Kok et al., 2016; Puraviappan, Dass, & Narayanan, 2007; Stamataki, Behar, & Brodsky, 2008; Stern, Feinmesser, Collins, Shott, & Cotton, 2002).

Studies reviewed indicated surgical management of sialorrhoea is effective (Khadivi et al., 2013; Khan et al., 2016; Kok et al., 2016; Puraviappan et al., 2007; Stamataki et al., 2008; Stern et al., 2002). Unfortunately, apart from children with CP, there have been very few clinical studies based on patients with any other sialorrhoea-related neurological disorders. Side effects were also reported, such as ranula, sialoadenitis, transient swelling of the mouth floor, pneumonia and operative urinary retention (Khadivi et al., 2013; Khan et al., 2016; Kok et al., 2016; Puraviappan et al., 2007). Dry mouth and dental caries were also reported in one study (Stern et al., 2002). Retrospective studies have indicated that there can be some gradual return of sialorrhoea (Khan et al., 2016; Stamataki et al., 2008). Although evidence in relation to the results of surgical intervention is of low quality and varied, the majority of patients still experience subjective improvements after surgery, and a positive improvement in social interaction in addition to increased self-esteem (Kok et al., 2016).

In current practices, there is a lack of statistics comparing the influence of sialorrhoea on life before and after the surgery (Kok et al., 2016). Data related to success and caregiver satisfaction following surgery are variable. Therefore, further studies are required in order to improve every individual patient's surgery outcome, and this includes high quality of evidence to assess the symptoms, patients' screening as well as the efficacy and safety of different surgery interventions (Lawrence & Bateman, 2018).

5 | DISCUSSION

A review of the literature that addresses the advantages and disadvantages of different sialorrhoea management approaches has been discussed here. From an analysis of the different management approaches, it seems that no single approach provides an ideal management protocol.

Although there are studies to support the short-term efficacy of behavioural intervention, it requires further studies to provide proof of long-term improvement (Van der Burg et al., 2009). Behavioural interventions have quite high relapse rates because it requires high

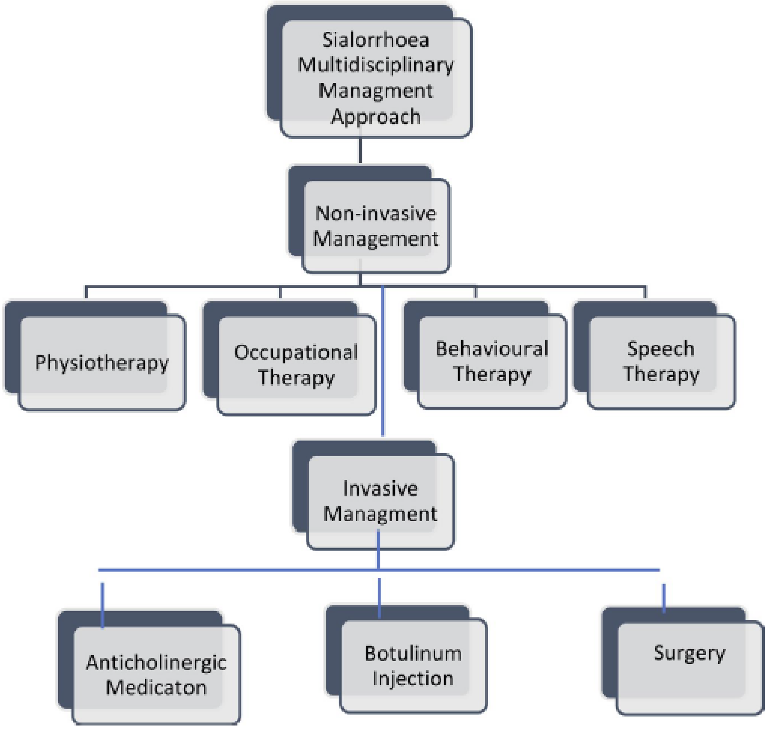

FIGURE 3 Sialorrhoea management follows hierarchical multidisciplinary approach, starting from non-invasive such as speech language therapy, physiotherapy, then moving to invasive approach such as anticholinergic medication, even surgery depending on the patient's needs and conditions

motivation level and more time (Lawrence & Bateman, 2018). In order to benefit from behavioural and motor oral therapy, patients need to have sufficient cognitive and oral motor capacities (Van der Burg et al., 2009; Kok et al., 2016). Of note, there is a lack of comparative trials regarding the efficiency of behavioural interventions and generally used medications (Fairhurst & Cockerill, 2011).

Anticholinergic drugs such as benztropine, glycopyrrolate and scopolamine have been used as first-line medication in the management of sialorrhoea. However, studies prove their effectiveness, these drugs often cause problematic adverse effects, their long-term effectiveness remains unknown (Mato et al., 2010), and there are insufficient data regarding their safety (Srivanitchapoom et al., 2014). With quite a range of anticholinergic drugs available, there is also a lack of evidence about which anticholinergic medication might provide the best balance between effectiveness and adverse side effects. Very little research has been carried out across a range of diseases, and the supporting evidence of the effectiveness of these drugs is limited.

One of the usual adverse effects of BoNT is mild dryness of the mouth. Therefore, the effectiveness and less side effects of BoNT-A or BoNT-B injections indicate the injections are effective in sialorrhoea treatment. However, the effect generally lasts only three to 6 months, and the repeat injection may lead to antibody formation and fading efficacy (Moller et al., 2015). Therefore, sialorrhoea also reverts slowly as the toxin effect wears off (Intiso & Basciani, 2012). Therefore, BoNT injection is not a long-term solution of sialorrhoea management. Furthermore, there is still a dearth of universally agreed guiding procedure regarding using BoNT to manage sialorrhoea.

Surgical procedures are shown to be effective, with minimalised adverse effects. As its effect is irreversible, surgery generates considerable controversy. From published studies, the surgical interventions were mostly performed on children with CP. It seems that there is lack of clinical studies of surgery on patients with ALS or any other sialorrhoea-related neurological disorders in the literature. And there are areas of uncertainty that require further research regarding its safety and effectiveness.

The majority of these studies have a relative restricted scope, either specifically focusing on a single disease category (MND, PD, ALS or CP) or specific population (paediatric or adult). In order to improve patients' sialorrhoea management outcomes, it requires further evidence to assess the signs and symptoms, patient selection, efficacy and safety of all the aforementioned management approaches. It is evident from the research to date that careful evaluation of the possible treatment alternatives for each individual patient is essential.

6 | LIMITATIONS

This review only included papers published in English. Studies reviewed, followed inclusion and exclusion criteria with a focus on different sialorrhoea management approaches. Furthermore, this review also followed the "gold standard" of RCT. This led to the removal of significant numbers of uncontrolled studies and studies that failed to meet the predefined screening criteria. However, some management studies also do not include enough RCT studies, especially in surgical management; nonetheless, case studies and retrospective cohort studies were included for synthesis. This review only gives a general synthesis of studies in the area of effectiveness and side effects. It does not provide further detailed synthesis of various doses of medication and administration techniques.

7 | CONCLUSION

The outcome data illustrate that sialorrhoea management requires all options to be available. It is also suggested that the first step of sialorrhoea management is to amend the causative issues that may make sialorrhoea worse, namely abnormal head position, airway problems, medications, severe abnormal occlusion and severe dental disease (Satow et al., 2004). Thereafter, first, it is essential, when practical, to propose the more functional interventions, such as oral motor therapy and behaviour therapy. If this is unmanageable, ineffective or inadequate, the next step is to propose a more invasive treatment, such as drug therapy or even surgery. Second, the management approach should mainly depend on the unique medical condition of the patient and the severity of sialorrhoea. Therefore, the multidisciplinary approach (Figure 3) should be a best practice option.

A multidisciplinary approach benefits from a holistic assessment from each professional from their unique expert perspectives, and thereby provides a comprehensive and holistic view of care. Multidisciplinary evaluation and intervention take more time, but it is a very appropriate means to manage sialorrhoea due to the fact that many patients may have different issues or challenges (Crysdale et al., 2006). Sialorrhoea is such a problem for many patients and their families that developing a more individualised therapeutic management approach would be essential to improve quality of life. Therefore, the management approach is undoubtedly an area that warrants further research.

8 | RELEVANCE TO CLINICAL PRACTICE

It is believed that the multidisciplinary healthcare approach allows a care team to provide comprehensive and optimal care of patients. A comprehensive understanding of different sialorrhoea management approaches will enable healthcare professionals to identify the signs and symptoms regarding sialorrhoea, to assist effective management implementation. The focus of the multidisciplinary management approach is to ensure that the needs of each patient and their carers are essential concerns in determining the appropriateness of the management approach for the patient. This will assist in optimising the management of sialorrhoea to improve quality of life and provide formative scope to develop an integrated care pathway.

CONFLICT OF INTEREST

There is no conflict of interest to declare.

ETHICAL APPROVAL

There is no ethical approval required undertaking this literature review.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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