# The oral health of people with serious mental illness

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**ABSTRACT**

The physical health needs of people with serious mental illness have been neglected for a long time (1), this has initiated the development of guidelines and recommendations from the British Society for Disability and Oral Health (BSDH) for the oral health care for people with serious mental illness (2). Guidelines recommend monitoring and advice and although they are well meaning, randomised controlled trial evidence to support the recommendations is missing (3, 4). Cochrane systematic reviews found no randomised controlled trials of oral health advice or monitoring for people with serious mental illness (5). A Cochrane systematic review of general physical health advice interventions for people with serious mental illness (6) found evidence to suggest such interventions could lead to people accessing more health services. For oral health there is some survey evidence to suggest regular dental check-ups have been found to be associated with better oral health (7), so if a monitoring and advice intervention can influence someone with serious mental illness to visit a dentist this may in turn improve their oral health.

A systematic review of 55 studies examining the prevalence of poor oral health and hygiene practices, dental treatment needs, and dental attendance of people with serious mental illness, was conducted to assess the extent to which people with serious mental illness brush their teeth and attend dental appointments. The majority of participants did not practice good oral hygiene, and were more likely not to have seen a dentist for a longer period of time than the general population. Those with serious mental illness also had more decayed teeth, more missing teeth, but fewer filled teeth, than the general population. Most of those with mental illness required some form of dental treatment ranging from oral hygiene instruction to complex dental treatment for those with shallow pockets or deep pockets in their teeth.

A narrative review of the knowledge and attitudes regarding oral health in populations with serious mental illness from service users, and mental health

and dental professionals' perspectives, found that individuals with serious mental illness were more likely to have poor oral health due to neglecting their oral hygiene and because they did not attend regular dental appointments. Previous negative experiences at dental appointments or general dental anxiety prevented individuals with a mental illness from seeking help until they experienced a dental emergency. The majority of service users reported that support from mental health nurses was helpful, even though nurses tended to report feeling unconfident and inadequately trained to provide this care.

A systematic review of randomised controlled trials of interventions for improving the oral health of people with serious mental illness identified four studies which all had such varied interventions and measured different outcomes that combining them in a meta-analysis was not possible. Providing toothbrushes appeared to improve the oral health of people with serious mental illness. Some of the interventions involved an education element which also significantly improved oral health.

A pragmatic cluster randomised controlled trial of an oral health intervention for people with serious mental illness involved 1074 service users from the Early Intervention in Psychosis teams in the East Midlands of England being randomised either to receive a dental intervention or standard care. The dental intervention involved completing a checklist with their Care Co-ordinator concerning their oral health and oral hygiene behaviour and the standard care simply involved continuing with standard care for 12 months before then completing the checklist. At baseline only 271/550 service users randomised to the dental intervention group completed dental checklists. Only 98/271 (36.1%) of service users returned a completed dental checklist at the 12 month follow up and for those allocated to standard care 91/524 (17%) returned a completed dental checklist at the 12 month follow up. The checklist did not improve oral health behaviour in people with serious mental illness.

The oral health of people with serious mental illness remains a vastly under researched area. Mental health professionals should receive training to improve their oral health care knowledge. Mental health professionals should also provide advice to their patients regarding their oral health, monitor oral health as part of standard care and support patients to attend regular dental check-ups. An effective intervention that can be used within standard care could significantly improve the quality of life for people with serious mental illness.

**OVERVIEW AND CONTRIBUTIONS TO THESIS**

The aims and objectives of this research project were to:

1. Systematically review the prevalence of oral health care practice, including the uptake of professional dental care for people with serious mental illness.
2. Review mental health professionals' knowledge of, and attitudes towards the oral health of people with serious mental illness.
3. Systematically review randomised controlled trials of oral health interventions for people with serious mental illness.
4. Conduct a pragmatic, cluster randomised controlled trial to examine whether a simple oral health intervention could lead to a clinically significant change in oral health behaviour for people with serious mental illness.

This research evolved from a Cochrane systematic review which found that there were no existing randomised controlled trials of oral health advice interventions for people with serious mental illness. With previous research indicating the high prevalence of oral health problems in people with mental illness (Chapter Two), mental health professionals' limited knowledge on oral health (Chapter Three) and guidelines indicating that oral health should be monitored as part of general physical health care for people with mental illness but with no evidence for its effectiveness (Chapter Four), the trial (Chapter Five) was designed.

I designed the three systematic reviews featured in Chapter Two, Chapter Three and Chapter Four, with support from my supervisors. The initial electronic search that was then adapted for each of the systematic reviews was approved by Ms Samantha Roberts, Librarian at Nottinghamshire Healthcare NHS Trust, and I undertook top-up searches as the project progressed to check for recent relevant literature. I was responsible for the selection of studies, data extraction and analysis in the systematic reviews with feedback and support from my supervisors. The initial idea for the trial (Chapter Five) was initiated by Professor Clive Adams and much of the preparation was conducted by Dr Andrew Clifton

who was the original Research Fellow on the project before it was further developed to become part of my PhD. I was part of a team of systematic reviewers who wrote the Cochrane systematic review in which the trial design was initially proposed. I was responsible for obtaining ethical approval from the Nottingham 1 ethics committee, which is one of the National Research Ethics Service (NRES) committees in the East Midlands. I was also responsible for gaining approvals from each of the three NHS trusts involved in the trial as well as recruiting the Early Intervention in Psychosis teams to the trial, obtaining consent from the team managers and Care Co-ordinators, and delivering the dental awareness training sessions with the support of Clinical Studies Officers from the NHS trusts. Statistical advice and support was provided by Professor Min Yang and Dr Boliang Guo.

## LIST OF ASSOCIATED PUBLICATIONS AND PRESENTATIONS

### Papers

Jones, Adams, Clifton, Simpson, Tosh, Callaghan, Liddle, Guo, Yang, Furtado. An oral health intervention for people with serious mental illness (Three Shires Early Intervention Dental Trial): study protocol for a randomized controlled trial. Trials. 2013, 14:158 doi:10.1186/1745-6215-14-158.

Jones, Adams, Clifton, Callaghan, Liddle, Buchanan, Aggarwal. A pragmatic cluster randomised controlled trial of an oral health intervention for people with serious mental illness (three shires early intervention dental trial). Trials 2013 14 (Suppl 1):P19.

Clifton, Tosh, Khokhar, Jones, Wells. Oral health advice for people with serious mental illness. Schizophrenia Bulletin. 2011 37 (3): 464-465.

Khokhar WA, Clifton A, Jones H, Tosh G. Oral health advice for people with serious mental illness. Cochrane Database of Systematic Reviews 2011, Issue 11. Art. No.: CD008802. DOI: 10.1002/14651858.CD008802.pub2.

### Posters

Jones, Adams, Buchanan, Aggarwal, Callaghan, Liddle. A cluster randomised controlled trial of an oral health intervention for people with serious mental illness. Poster presentation at the 2nd UK Clinical Trials Methodology Conference: Methodology Matters, Edinburgh, November, 2013.

Jones. A cluster randomised controlled trial of an oral health intervention for people with serious mental illness. Poster presentation at the NIHR Infrastructure Experimental Medicine Research Training Camp, Ashridge Business School, June 2013.

Jones, Adams, Buchanan, Aggarwal, Callaghan, Liddle. A cluster randomised controlled trial of an oral health intervention for people with serious mental

illness: East Midlands' baseline data. Poster presentation at the Health Services Research Network. Nottingham, June 2013.

Jones. A pragmatic cluster randomized controlled trial of an oral health intervention for people with serious mental illness. School of Community Health Sciences PGR Conference, University of Nottingham, December 2012.

Jones, Adams, Simpson, Clifton, Callaghan, Liddle. The three shires early intervention dental trial: a real world cluster randomised controlled trial. Poster presentation at the East Midlands & South Yorkshire MHRN Hub Annual Research Meeting. Nottingham. March 2012.

Jones, Adams, Simpson, Tosh, Clifton, Khokhar, Callaghan, Liddle. From an empty review to a full trial: not a painful extraction. Poster Presentation at the 17th Annual Meeting of UK and Ireland-based Contributors to The Cochrane Collaboration. Loughborough. March 2012.

**Oral Presentations**

Jones, Adams, Buchanan, Aggarwal, Callaghan, Liddle. A cluster randomised controlled trial of an oral health intervention for people with serious mental illness: East Midlands' baseline data. Oral presentation at the Institute of Mental Health Research Day. Nottingham, May 2013.

Jones, Adams, Simpson, Clifton, Callaghan, Liddle. Three shires early intervention dental trial: A pragmatic cluster randomised controlled trial – progress so far. Thematic session at the 11th World Congress for the World Association for Psychosocial Rehabilitation. Milan, Italy. 10-13th November 2012.

Jones. Three shires early intervention dental trial: A pragmatic cluster randomised controlled trial. Oral presentation at the University of Nottingham, School of Medicine, Division of Psychiatry Postgraduate Research Seminar Series. October, 2012.

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## CHAPTER ONE. Introduction

The aim of this chapter is to give a brief overview of the relevant concepts and background to the later chapters. This is not a literature review but a discussion to understand what is meant by the terms oral health and serious mental illness and the implications that poor oral health can have.

### 1.1 Serious mental illness

Mental illness is one of the most prevalent health problems (8), and can be defined as "*a clinically significant behavioural or psychological syndrome associated with distress, disability or significant increased risk of suffering pain, disability, or an important loss of freedom or death*" (2) (p.192). Serious mental illness includes affective disorders, depressive disorders, anxiety disorders, eating disorders, panic disorders and psychotic disorders (9). The focus within this thesis will mainly be psychotic disorders. Psychotic disorders can affect the way people are able to function in society due to disordered perceptions, emotions and sense of reality (9). The Diagnostic and Statistical Manual of Mental Disorders 5 defines the schizophrenia spectrum and other psychotic disorders as an "*abnormality of delusions, hallucinations, disorganized thinking, grossly disorganized or abnormal motor behaviour and negative symptoms"* (10) (p.87). The cause of psychotic disorders is not known, however both genetic and environmental factors may play a part (11). People with psychotic disorders are often treated with a variety of psychotropic medications or psychological interventions in inpatient or community settings.

Individuals with serious mental illness tend to have a higher mortality rate than the general population estimated at a reduction of 10 years (12); part of this excess mortality is attributable to accidents or suicide but a significant amount is due to physical illnesses that could be preventable (13). There is great stigma associated with mental illness and this has been cited as a possible reason for the increased mortality rate as expensive or time consuming medical treatment may not be offered to people with a mental illness or may only be offered at an advanced stage (13-15).

### 1.2 Oral health

Oral health is an important part of general physical health and good oral health is essential for self-esteem, self-confidence and overall quality of life (1, 16). Oral health is not just about having healthy teeth it also includes the surrounding tissues which enable people to live to an acceptable level without disease, discomfort or embarrassment (16).

Coronary heart disease, stroke, chronic lung disorders and diabetes have all been directly linked to poor oral health and it can also lead to chronic stress or depression (17-23). Poor oral health has been shown indirectly to affect breathing and speaking as well as being detrimental to self-image and impeding normal social interactions (1).

### 1.3 Oral health in individuals with mental illness

People with mental illness are likely to experience more oral health problems and require more dental treatment than the general population (2). Indeed, the Department of Health 'Choosing Better Oral Health' guidelines found that people with mental illness generally had "*fewer teeth, more untreated decay and more periodontal disease than the general population*" (16) (p.17). The oral health of females with mental illness is likely to be worse than for males as shown by higher DMFT scores; poor oral health may also increase significantly in older individuals and those who had been institutionalised for longer (24). More severe mental illness has also been associated with more severe dental disease (25-27).

Many people who manage to control symptoms of their mental illness may not have oral health problems that are related to their mental health (28). However, when a person has a serious mental illness their symptoms deteriorate: their oral health may not be a priority, and so it is neglected and deteriorates (2). The poor oral health of people with mental illness has been the focus of an increasing amount of research over the last decade. Prevalence rates of suboptimal oral health have been found to be 61% higher in individuals with mental illness

compared to the general population, and the worst oral health has been identified in individuals diagnosed with schizophrenia over any other serious mental illness (29). Type and severity of mental illness, motivation, mood, socio-economic status, smoking, alcohol intake, medication, and the knowledge and experience of the multidisciplinary mental health team are factors known to influence oral health for people with serious mental illness (1, 2, 30).

People with mental illness often report that staff and carers never ask them about dental problems (31). Dental needs of people with mental illness have been overlooked for a long time (30, 32-34), and they are often excluded from many health promotion programs (1). Most dental professionals have limited experience in providing care for people with psychiatric disorders (35). Despite the need for intervention, oral health programs for people with mental illness are rare (36).

The latest NICE guidelines (37) for the treatment and management of psychosis and schizophrenia in adults contains updates regarding monitoring physical health. When an individual with serious mental illness is referred to secondary care services, the mental health service should maintain responsibility for monitoring general physical health and any effects of antipsychotic medication for at least the first 12 months or until the individual's mental health has stabilised. After this time, the responsibility for monitoring the individuals' general physical health may be transferred to primary care services under shared care arrangements when an annual health check should be performed. The health check should cover physical health problems that often occur in people with serious mental illness and include oral health.

Barriers exist in organization and financing of the care needed as well as in proposing strategies to enhance the delivery of appropriate treatment (38). Oral health services remain underutilized, and there is a high prevalence of perceived barriers by individuals with serious mental illness to receiving dental care (39).

Poor oral health in individuals with mental illness can be due to overzealous tooth brushing during a manic stage or disinterest in oral hygiene during a depressive episode (40). People with mental illness may be more prone to dental problems because of the side effects of psychotropic medication. Selective serotonin reuptake inhibitors (SSRIs), antidepressants, phenothiazines and benzodiazepines can cause xerostomia (lack of saliva or dry mouth) (25). Saliva fights plaque and helps to strengthen tooth enamel, and a lack of saliva can lead to caries, periodontal disease, gingivitis, glossitis, stomatitis, parotiditis, fissured tongue, mouth ulcers and oral candidiasis, which puts individuals at greater risk for requiring dental treatment, restorations and extractions (1, 25, 41, 42). The symptoms of these side effects are more likely to occur when augmenting antipsychotic medication with anticholinergic medication (42), and can be made worse when attempts are made to alleviate the feeling of dry mouth by consuming sweets and fizzy drinks (32), which can increase the risk of caries in their own right. Some medication, in particular clozapine, has the opposite effect and can result in sialorrhea (excessive salivation) which can result in dribbling and eventually facial soreness (43).

First generation antipsychotics are associated with many side effects including extrapyramidal effects like dyskinesia and akathisia and dystonia; these side effects are less common but are particularly distressing for the individual concerned and may interfere with dental treatment (9). Early side effects can include spasms of the muscles in the face, tongue and neck (44). These movement disorders can prevent individuals from taking effective care of their teeth, can also cause damage to teeth and can interfere with dental treatments (44). People with mental illness may also develop temporomandibular disorders (TMD) (45).

Serious mental illness may make people more likely to lose the motivation or ability to adopt and maintain good oral hygiene behaviour (32). Many only attend dental appointments when they have serious problems and do not regularly attend routine dental check-ups (32, 46). It has also been reported that

for people with mental illness some dentists may be more likely to extract teeth that are causing problems instead of treating them (1, 29, 32), as this patient group is likely to require longer appointments than people from the general population. Appointments for people with mental illnesses may take longer due to a lack of understanding, increased anxiety, or a preoccupation with other symptoms (1). Few dentists may be familiar with the complex clinical needs of people with serious mental illness, which may prevent people with serious mental illness from finding a dentist who is willing and able to treat them (42). Other lifestyle factors including links between smoking and poor diet for people with mental illness have been identified as putting people with serious mental illness at greater risk of experiencing dental problems (1).

Some dental symptoms may be the first presentation of symptoms of mental illness, like facial problems, palatal erosion, facial trauma and temporomandibular joint dysfunction (29, 46). Gingival recession and tooth abrasion can indicate mania or perfectionism, due to overzealous brushing (44). Dental problems may also be involved in hallucinations or delusions by people with mental illness (1). Dental anxiety is a common problem in the general population, for patients and dental practitioners alike, as people with dental anxiety will often avoid necessary treatment and will only seek treatment when they are in a significant amount of pain, which then makes treatment more complex (47). There is a well identified link between dental anxiety, avoidance behaviour, and dental problems (47-50).

The 'advice' component of the routine dental appointment can vary widely, but should include some aspect of professional advice regarding the prevention of oral disease (51). The advice should include instructions on what constitutes appropriate oral hygiene behaviour to prevent dental caries and periodontal disease. This could include making sure that toothpaste contains fluoride, using an appropriate toothbrushing technique, and flossing. Dietary advice regarding sugar intake and advice about smoking cessation as well as alcohol consumption should also be given.

In summary, people with serious mental illness have been found to have poor oral health when compared to the general population. There is a lack of research on interventions to improve the oral health of this population. This thesis will explore the prevalence of poor oral health and hygiene practices of people with serious mental illness to gain a better understanding of the true extent of the problem. Possible reasons for the poor oral health will be reviewed by looking at knowledge of and attitudes towards oral health from service users, and mental health and dental professionals' point of view. Previous studies that have implemented an oral health intervention for people with serious mental illness will be reviewed to gain an understanding of which direction a new intervention should take.

### 1.4 Aims and objectives

The aims and objectives of this thesis are to:

1. Review the prevalence of poor oral health and hygiene practices, dental treatment needs, and dental attendance of people with serious mental illness.
2. Review the knowledge and attitudes regarding oral health in populations with serious mental illness from service users, and mental health and dental professionals' perspectives.
3. Review existing randomised controlled trials of oral health interventions for people with serious mental illness.
4. Conduct a pragmatic, cluster randomised controlled trial to examine whether a simple oral health intervention could lead to a clinically significant change in oral health behaviour for people with serious mental illness.

The next chapter will explore the prevalence of poor oral health and hygiene practices, dental treatment needs, and dental attendance of people with serious mental illness within the context of a systematic review.

## CHAPTER TWO. Prevalence of poor oral health and hygiene practices, dental treatment needs, and dental attendance of people with serious mental illness: A systematic review

### 2.1 Background

Previous research has identified a link between serious mental illness and poor oral health (1). The Department of Health 'Choosing Better Oral Health' guidelines found that, compared to the wider general population, people with mental illness generally have more untreated tooth decay and fewer teeth (16). Poor oral health may result in pain and oral disease. This can make it difficult for an individual to bite, chew, smile, speak, and it may reduce their self-esteem (16). Improving the oral health of those with serious mental illness is consequently a major issue for dental and mental health services. Indeed, when a person suffers from mental illness their oral health may not be a priority, and so it can be neglected and deteriorates (2). However, it is also the case that people who manage to control symptoms of their mental illness may not have oral health problems that are specifically mental health related (28).

In the past decade there has been continued growing interest in this area with a number of studies investigating the oral health of people with mental illness. These have mainly backed up previous findings, that is oral health for people with mental illness is considerably worse than the general population and they are likely to experience more oral health problems and require more dental treatment (2, 25, 26, 31, 33, 39, 46, 52-55). Despite these conclusions, the dental needs of people with mental illness have continued to be overlooked (30, 32-34), and they are often excluded from health promotion programs (1). Moreover, individuals with mental illness often report that staff and carers never ask them about dental problems (31). Prevalence rates of suboptimal oral health have been found to be 61% higher in individuals with mental illness compared to the general population, and the worst oral health has been identified in individuals diagnosed with schizophrenia over any other mental illness (29). Type and

severity of mental illness, motivation, mood, socio-economic status, smoking, alcohol intake, medication, and the knowledge and experience of the multidisciplinary mental health team are factors known to influence oral health for people with serious mental illness (1, 2, 30).

Oral health in mental health has become an increasingly popular topic over recent years and a large number of studies presenting the poor oral health of people with serious mental illness have been published (3, 32, 41, 56-67). There have also been attempts to bring together these findings in reviews. For example, a recent systematic review summarised studies assessing the prevalence of poor oral health in adults with serious mental illness and found a suboptimal oral health rate of 61% (29). In addition, a recent meta-analysis found that people with serious mental illness were 3.4 times more likely to have lost all their teeth than the general population (68). Those with serious mental illness also had more decayed, more missing, and fewer filled teeth than the general population. They concluded that although dental health had been improving in recent years for the general population, it had not for people with serious mental illness. However this review excluded studies focusing on outcomes such as poor oral hygiene and studies lacking a control group (68). If individuals with serious mental illness do not practice good oral hygiene behaviour then their oral health is unlikely to improve, so outcomes measuring this are important. As this review also excluded studies that did not have a control group as a comparison, data from many surveys that may include oral hygiene behaviour outcomes have been overlooked.

The purpose of the present review is to examine oral state, oral hygiene practice, dental treatment needs, and professional dental care for people with serious mental illness. Other reviews have tended to focus on indices of poor oral health such as the number of decayed, missing and filled teeth rather than on oral hygiene (such as tooth-brushing) and preventative dental treatment (68). Dental disease can often be prevented by good oral hygiene and can be identified earlier and therefore require less complex treatment if regular dental visits are

made. Findings from this review will provide a summary of the extent of the poor oral hygiene practices and lack of professional dental treatment received by people with serious mental illness. These findings could then be used to develop effective interventions to improve oral health in this specific population.

## 2.2 Method

### 2.2.1 Search Strategy

MEDLINE, PsycINFO, CINAHL and EMBASE were searched using the following terms in December 2013: ((chronic$ or severe$ or serious$ or persistent$) adj (mental$ or psych$) adj (disorder$ or ill$)) or (schizo$ or psychotic$ or psychosis or psychoses) and ((tooth or teeth or dent* or (oral adj2 health) or (oral adj2 hygiene)). No language or date restrictions were used.

### 2.2.2 Inclusion and exclusion criteria

The focus of this review was studies that surveyed the oral health of people with serious mental illness. To be eligible for inclusion, studies had to have a patient-oriented oral health objective and primary outcome with useable data. Studies conducted in any setting involving people of any age or sex who were diagnosed with serious mental illness that was either author-defined or cited standardised diagnostic criteria (e.g. Diagnostic and Statistical Manual of Mental Disorders (DSM) or International Classification of Diseases (ICD)) were included. Baseline data only were extracted from studies that involved an intervention. We excluded studies that involved a majority of people with a diagnosis of learning disability or dementia as there are separate recommendations and guidelines for these populations (69, 70).

### 2.2.3 Outcomes

The following outcomes were included:

- Oral Hygiene (owning a toothbrush, replacing a toothbrush, frequency of tooth brushing, use of mouthwash, use of dental floss).
- Dental Appointment (registered with a dentist, regular dental appointments (≤ two years), last dental appointment).

- Decayed, Missing or Filled Teeth (DMFT) (71). This index is a key measure of the prevalence of dental caries and the number of teeth which is expressed as the total number of teeth that are decayed (D), missing (M), or filled (F) in an individual. Scores per individual can range from 0 to 28 or 32, depending on whether the third molars are included in the scoring as this is optional.
- Community Periodontal Index of Treatment Needs (CPITN) (72). This measure is often used as a screening or monitoring tool to determine the periodontal treatment needs of an individual. The mouth is divided into six sextants and a dental examination is done with a special dental probe. A score is given based on: 0 = no periodontal disease, 1 = bleeding on probing, 2 = calculus with plaque seen or felt by probing, 3 = shallow pocket 4 – 5 mm, 4 = deep pocket 6 mm or more, x = when there is only 1 tooth or no teeth.

### 2.2.4 Quality assessment

The quality of studies was assessed using the following criteria adapted from Boyle (1998) (73) and Loney et al (1998) (74):

- Was the sampling procedure clearly described and was random sampling employed?
- Was there ≥75% response rate if random sampling utilised?
- Were inclusion/exclusion criteria reported and adhered to?
- Was there a clear data collection period reported?

## 2.3 Results

The electronic search identified 1057 citations of which 89 potentially relevant papers were obtained for further inspection. After assessing the full papers for eligibility against the specified inclusion and exclusion criteria, 34 studies were excluded and 55 included. Reasons for exclusion involved the participants not having an eligible diagnosis (n=8), not reporting useable data for relevant outcomes (n=10), not measuring outcomes included in this review (n=11),

combining data from other studies (n=1) and retrospectively reviewing patient records (n=4) (see Table 1).

Table 1. Excluded studies

| Study ID | Reason for exclusion |
|---|---|
| Adam 2006 (75) | Diagnosis - Majority of participants diagnosed with dementia. |
| Al-Hiyasat 2006(76) | Outcomes - No useable outcomes. |
| Almomani 2009 (41) | Outcomes - No useable outcomes. |
| Barnes 1988 (40) | Outcomes - No useable data from outcomes. |
| Bhansali 2008 (77) | Diagnosis - Participants were geriatric psychiatric inpatients, those with schizophrenia excluded and The Bristol Activities Scale of Daily Living scale was used – this scale was designed to assess daily living abilities of people with dementia. It was therefore assumed that the majority of participants would have been diagnosed with dementia. |
| Bilder 2013 (78) | Outcomes - No useable data from outcomes. |
| Burchell 2006 (79) | Outcomes - No useable data from outcomes. |
| Chu 2013 (61) | Outcomes - No useable outcomes. |
| Dickerson 2003 (39) | Outcomes - Oral health not main outcome. |
| Dixon 1999 (80) | Outcomes - Oral health not main outcome. |
| Gowda 2007 (81) | Outcomes - No useable data from outcomes. |
| Heaton 2013 (82) | Outcomes - Retrospective survey of records. |
| Horst 1992 (83) | Outcomes - Focused on nurses' attitudes, is not a survey examining the oral health of people with a serious mental illness. |
| Jamelli 2010 (84) | Outcomes - No useable data from outcomes. |
| Jurek 1993 (85) | Outcomes - No useable outcomes. |
| Kilbourne 2007 (33) | Outcomes - No useable outcomes. |
| Klinge 1979 (86) | Outcomes - No useable data from outcomes. |
| Kossioni 2013a (87) | Outcomes - No useable outcomes. |
| Kossioni 2013b (88) | Outcomes - No useable outcomes. |
| Kubota 1988 (89) | Outcomes - No useable data from outcomes. |

| | |
|---|---|
| Mun 2013 (90) | Outcomes - No useable outcomes. |
| Nielsen 2009 (91) | Outcomes - Retrospective survey of records. |
| Okoro 2012 (92) | Outcomes - Retrospective survey of records. |
| Ponizovsky 2009 (55) | Outcomes - Review combining data from two studies. |
| Portilla 2009 (93) | Outcomes - No useable outcomes. |
| Rudolph 1993 (94) | Diagnosis - Participants had “congenital abnormalities, mental retardation and other psychiatric populations.” |
| Savic-stankovic 2011 (95) | Diagnosis - Participants were “institutionalized mentally retarded”. |
| Sjogren 2000 (96) | Outcomes - No useable outcomes. |
| Tamaki 2011 (97) | Diagnosis - Study focused on people attending a dental clinic and then assessing them for a psychiatric diagnosis. |
| Tanasiewicz 2011 (98) | Outcomes - No useable data from outcomes. |
| Tang 2004 (46) | Outcomes - No useable data from outcomes. |
| Viglid 1993 (99) | Diagnosis - Half of the participants were diagnosed with dementia. |
| Whittle 1987 (100) | Diagnosis - Participants diagnosed with early stages of dementia. |
| Whyman 1995 (101) | Diagnosis - 75% of participants were reported as “mentally retarded”. |

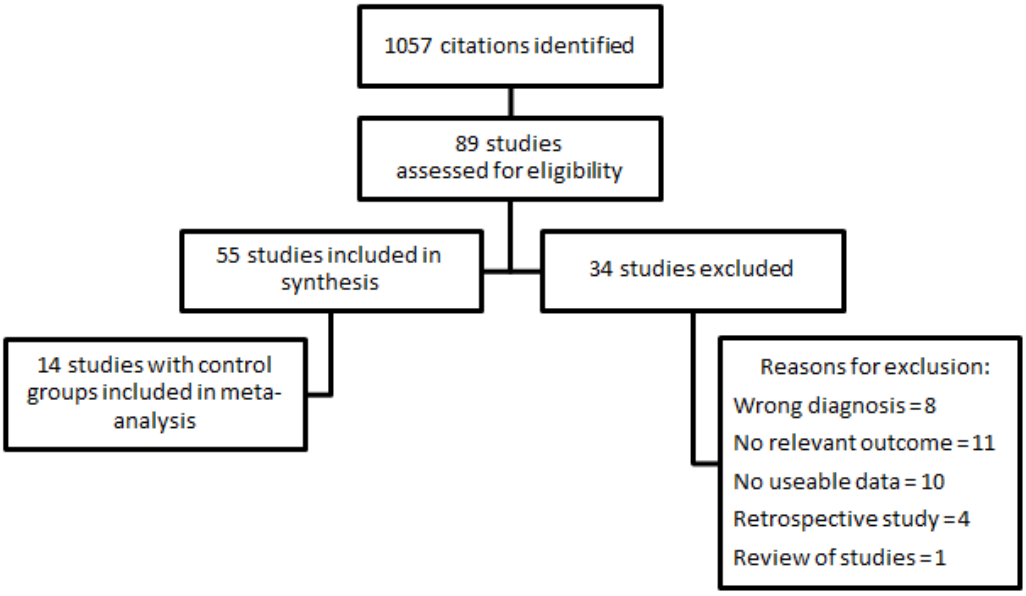


Figure 1. Flow diagram

The 55 studies included in this review provide data on a total of 9469 individuals with serious mental illness from 25 countries (Table 2). The majority of studies were conducted in inpatient mental health units (n=31) and two studies recruited participants from both inpatient and outpatient settings (102, 103). Most studies were a survey of a specific population at a specific time point with 14 also including a general population control group. Only 24 studies cited having used formal diagnostic criteria (Table 3).

Table 2. Included study details and participant demographics

| Study ID | Country | Setting | Control Group | N | N invited | Response % | Age | | | Sex | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | mean | SD | range | male | % | female | % |
| Adeniyi 2011 | Nigeria | Outpatients | | 105 | | | 39.2 | 13.8 | 14-76 | 47 | 45 | 58 | 55 |
| Al-Dabbas 2005 | Jordan | Inpatients | | 120 | 153 | 78 | 37 | | | | | | |
| Al-Mobeeriek 2012 | Saudi Arabia | Outpatients | Yes | 100 | | | | | 20-50 | 41 | 22.3 | 59 | 32.1 |
| Angelillo 1995 | Italy | Inpatients | | 297 | 316 | 94 | 55.1 | | 24-95 | 165 | | 132 | |
| Arnaiz 2011 | Spain | Outpatients | Yes | 66 | 77 | 86 | 40.4 | 11.2 | | 42 | 64 | 24 | 36 |
| Bertard-Gounot 2013 | France | Inpatients | | 161 | 185 | 87 | 56.9 | 17.5 | 18-90 | 95 | 59 | 66 | 41 |
| Buunk-Werkhoven 2010 | Netherlands | Inpatients | | 39 | | | 37.9 | 9.6 | | 39 | 100 | | |
| Chalmers 1998 | Australia | Outpatients | | 138 | | | 46.5 | 14.5 | | 85 | 62 | 53 | 38 |
| Chu 2010 | Taiwan | Inpatients | | 1108 | 1468 | 75 | 50.8 | 10.8 | | 809 | 73 | 299 | 27 |
| Eltas 2012 | Turkey | Outpatients | | 53 | | | | | | 24 | 45 | 29 | 55 |
| Farrahi-Avval 2008 | USA | Inpatients | | 94 | 451 | 21 | | | | 65 | | 29 | |
| Flammer 2009 | Germany | Inpatients and Outpatients | Yes | 120 | | | 45.3 | 15.6 | | 62 | | 58 | |
| Ghaffarinejad 2013 | Iran | Inpatients | | 193 | | | | | | | | | |
| Gopalakrishnapillai 2012 | India | Inpatient | | 165 | 185 | 89 | 41.94 | | | 97 | 58.8 | 68 | 41.2 |
| Gurbuz 2010 | Turkey | Inpatients | | 491 | 505 | 97 | 52.84 | 12.37 | 22-84 | 258 | 53 | 233 | 48 |
| Hashimoto 2005 | Japan | Outpatients | Yes | 26 | | | | | | | | | |
| Hede 1992 | Denmark | Outpatients | | 84 | 120 | 70 | | | | 30 | | 54 | |
| Hede 1995 | Denmark | Inpatients | | 278 | 335 | 83 | | | | 164 | | 114 | |
| Hsieh 2012 | Taiwan | Inpatients | | 100 | | | | | | | | | |
| Janardhanan 2011 | USA | Outpatients | Yes | 198 | | | 61.5 | 5.6 | | 51 | | | |
| Jayakumar 2011 | India | Inpatients | | 250 | | | | | 50-75 | | | | |
| Jovanovic 2010 | Serbia | Inpatients | Yes | 186 | 240 | 78 | | | 20-59 | 87 | 47 | 99 | 53 |
| Jyoti 2012 | India | Inpatients | | 141 | | | 37.36 | 12.87 | 16-75 | | 47 | | 53 |
| Kebede 2012 | Ethiopia | Outpatients | | 240 | 384 | 63 | 29.9 | 9.79 | 15-68 | 168 | 70 | 72 | 30 |
| Kenkre 2000 | India | Inpatients | | 129 | 153 | 84 | | | 15-75 | 90 | 59 | 63 | 41 |
| Khokhar 2011 | UK | Inpatients | | 31 | 34 | 91 | | | 22-76 | 21 | | 10 | |

| | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kossioni 2012a | Greece | Inpatients | | 111 | | | 73 | | 57-94 | 41 | | 70 | |
| Krunic 2013 | Serbia | Inpatients | Yes | 61 | | | 36.7 | 6.8 | | | | 61 | 100 |
| Kumar 2006 | India | Inpatients | | 180 | 220 | 82 | 36.7 | | | 105 | 58.3 | 75 | 41.7 |
| Lalloo 2013 | Australia | Outpatients | | 50 | | | 40 | | 20-83 | | | | |
| Lewis 2001 | UK | Inpatients | | 326 | 469 | 70 | 71.1 | 18.5 | | 143 | | 183 | |
| Lynch 2005 | UK | Inpatients | | 41 | 50 | 82 | 59.7 | 19.7 | | | 61 | | 49 |
| McCreadie 2004 | UK | Outpatients | | 93 | | | | | | | | | |
| Mirza 2001 | UK | Inpatients | | 26 | 50 | 52 | 39 | | | 14 | | 15 | |
| Nikfarjam 2013 | Iran | Inpatients | | 123 | | | 38.81 | 10.46 | | | | | |
| Patel 2012 | UK | Outpatients | | 89 | 112 | 79 | | | | 57 | 64 | | |
| Persson 2009 | Sweden | Outpatients | | 113 | 144 | 78 | 43 | 12 | 21-63 | 46 | | 67 | |
| Purandare 2010 | UK | Outpatients | Yes | 103 | | | 78.7 | | 66-96 | 37 | 36 | | |
| Rahman 2013 | Malaysia | Outpatients | | 75 | | | 34.7 | 11,14 | | 39 | 52 | | |
| Ramon 2003 | Israel | Inpatients | | 431 | | | 54 | | 18-96 | 250 | | 181 | |
| Rehka 2002 | India | Inpatients | Yes | 326 | | | 34.14 | | 17-90 | 203 | | 123 | |
| Sacchetto 2013 | Brazil | Outpatients | | 40 | | | 35.08 | 10.83 | | 20 | 50 | 20 | 50 |
| Sayegh 2006 | Jordan | Outpatients | Yes | 40 | 42 | 95 | 34.77 | | 20-55 | 20 | | 20 | |
| Shah 2012 | India | Outpatients | Yes | 133 | | | 40.2 | | | 88 | 66 | 45 | 34 |
| Stiefel 1990 | USA | Outpatients | Yes | 37 | | | 33.4 | 8.6 | | 24 | 65 | 13 | 35 |
| Stevens 2010 | UK | Inpatients | | 65 | 155 | 42 | | | | | | | |
| Tani 2012 | Japan | Inpatients | | 523 | 550 | 95 | 55.6 | 13.4 | 18-87 | 297 | 57 | 226 | 43 |
| Teng 2011 | Taiwan | Inpatients | | 200 | | | 41 | | | 125 | 63 | 75 | 38 |
| Thomas 1996 | Greece | Inpatients | | 249 | | | 50.35 | 13.7 | | 108 | 43 | 141 | 57 |
| Ujaoney 2010 | India | Inpatients and Outpatients | Yes | 100 | | | | | | 44 | 44 | 56 | 56 |
| UHK 2006 | Hong Kong | Outpatients | | 132 | 250 | 53 | 41 | 8 | 20-62 | 77 | 58 | 55 | 42 |
| Velasco-Ortega 2012 | Spain | Inpatients | Yes | 50 | | | 69.6 | 6.7 | | 25 | 50 | 25 | 50 |
| Velasco 1997 | Spain | Inpatients | | 565 | 850 | 66 | 58 | | | 347 | | 218 | |
| Wieland 2010 | Australia | Outpatients | | 20 | | | 34.1 | 10.5 | 22-63 | | 45 | | 55 |
| Zusman 2010 | Israel | Outpatients | | 254 | | | 52.5 | 14.5 | 18-91 | 156 | | 98 | |

Table 3. Mental health diagnoses

| Study ID | Diagnostic Criteria | Psychotic Disorders | | Mood Disorders | | Anxiety Disorders | | Personality Disorder | | Learning Disability | | Organic Disorder | | Other | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | n | % | n | % | n | % | n | % | n | % | n | % | n | % |
| Adeniyi 2011 | | 18 | 17 | 37 | 35 | 15 | 14 | | | | | | | 35 | 34 |
| Al-Dabbas 2005 | | 51 | 42 | 56 | 47 | | | | | | | | | 13 | 11 |
| Al-Mobeeriek 2012 | | | | | | | | | | | | | | | |
| Angelillo 1995 | DSM-III-R | 193 | 65 | 32 | 11 | | | | | | | 61 | 20 | 11 | 4 |
| Arnaiz 2011 | DSM-IV-TR | 66 | 100 | | | | | | | | | | | | |
| Bertard-Gounot 2013 | ICD-10 | 59 | 36.6 | 34 | 21.1 | | | 4 | 2.5 | 12 | 7.5 | 13 | 8.1 | 39 | 24.2 |
| Buunk-Werkhoven 2010 | | | | | | | | | | | | | | | |
| Chalmers 1998 | | 101 | 73.2 | 23 | 16.7 | 3 | 2.2 | 4 | 2.9 | 11 | 8 | | | 3 | 2.2 |
| Chu 2010 | ICD-9 | 1108 | 100 | | | | | | | | | | | | |
| Eltas 2012 | DSM-IV-TR | 53 | 100 | | | | | | | | | | | | |
| Farrahi-Avval 2008 | | 73 | 78 | 21 | 22 | | | | | | | | | | |
| Flammer 2009 | DSM-IV | 120 | 100 | | | | | | | | | | | | |
| Ghaffarinejad 2013 | | | | | | | | | | | | | | | |
| Gopalakrishnapillai 2012 | | | | | | | | | | | | | | | |
| Gurbuz 2010 | | 359 | 73.1 | | | | | | | 118 | 24 | 14 | 2.9 | | |
| Hashimoto 2005 | | 13 | 50 | 5 | 19 | | | | | 1 | 4 | 1 | 4 | 6 | 23 |
| Hede 1992 | | 63 | 76 | 9 | 10 | | | | | | | | | 12 | 14 |
| Hede 1995 | ICD-8 | 136 | 48 | 30 | 11 | | | 44 | 16 | | | | | 68 | 25 |
| Hsieh 2012 | DSM-IV | 100 | 100 | | | | | | | | | | | | |
| Janardhanan 2011 | DSM-IV | 198 | 100 | | | | | | | | | | | | |
| Jayakumar 2011 | ICD-10 | | | | | | | | | | | | | | |
| Jovanovic 2010 | ICD-10 | 132 | 71 | 9 | 5 | | | | | | | | | 45 | 24 |
| Jyoti 2012 | | | 73 | | 21.3 | | | | | | | | | | 5.7 |
| Kebede 2012 | | 42 | 17.5 | 162 | 67.5 | 20 | 8.3 | | | | | | | 16 | 6.7 |
| Kenkre 2000 | | 96 | 63 | 24 | 16 | | | | | | | 25 | 16 | 8 | 5 |
| Khokhar 2011 | | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Kossioni 2012a | | 48 | 53.9 | 18 | 20.2 | | | | | | | | | 23 | 25.9 |
| Krunic 2013 | | | | | | | | | | | | | | | |
| Kumar 2006 | ICD-10 | | | | | | | | | | | | | | |
| Lalloo 2013 | | 47 | 94 | 1 | 2 | | | | | | | | | 2 | 4 |
| Lewis 2001 | | 83 | 26 | 65 | 20 | | | 3 | 1 | 6 | 2 | 153 | 46 | 16 | 5 |
| Lynch 2005 | | 34 | 83 | | | | | | | | | | | 7 | 17 |
| McCreadie 2004 | DSM-IV | 93 | 100 | | | | | | | | | | | | |
| Mirza 2001 | | | | | | | | | | | | | | | |
| Nikfarjam 2013 | DSM-IV | 123 | 100 | | | | | | | | | | | | |
| Patel 2012 | | | | | | | | | | | | | | | |
| Persson 2009 | DSM-IV | 37 | 33 | 34 | 30 | 24 | 21 | | | | | | | 18 | 16 |
| Purandare 2010 | | 15 | 15 | 39 | 38 | | | | | | | 35 | 34 | | |
| Rahman 2013 | | 55 | 73.4 | 10 | 13.3 | | | | | | | | | 10 | 13.3 |
| Ramon 2003 | ICD-10 | 316 | 73.2 | 21 | 4.9 | | | | | | | 71 | 16.6 | 23 | 5.3 |
| Rehka 2002 | ICD-10 | | | | | | | | | | | | | | |
| Sacchetto 2013 | | 19 | 47.5 | 4 | 10 | | | 1 | 2.5 | 3 | 7.5 | | | 13 | 32.5 |
| Sayegh 2006 | ICD-10 | 23 | 57 | 17 | 43 | | | | | | | | | | |
| Shah 2012 | | 9 | 6.8 | 46 | 34.6 | 37 | 27.8 | | | | | | | 41 | 30.7 |
| Stiefel 1990 | DSM-III | 29 | 78.4 | 5 | 13.5 | | | 2 | 5.4 | | | 1 | 2.7 | | |
| Stevens 2010 | | | | | | | | | | | | | | | |
| Tani 2012 | ICD-10 | 523 | 100 | | | | | | | | | | | | |
| Teng 2011 | | 122 | 61 | 52 | 26 | | | | | | | 22 | 11 | 4 | 2 |
| Thomas 1996 | DSM-III | 249 | 100 | | | | | | | | | | | | |
| Ujaoney 2010 | ICD-10 | 42 | 32 | 27 | 20 | 15 | 11 | | | | | | | 16 | 12 |
| UHK 2006 | | | | | | | | | | | | | | | |
| Velasco-Ortega 2012 | DSM-IV-TR | 28 | 56 | 1 | 2 | | | | | | | | | 21 | 42 |
| Velasco 1997 | | | | | | | | | | | | | | | |
| Wieland 2010 | | 17 | 85 | 2 | 10 | | | 1 | 5 | | | | | | |
| Zusman 2010 | ICD-10 | 209 | 82.4 | 4 | 1.5 | | | | | | | 41 | 16.1 | | |

### 2.3.1 Quality appraisal

Only 32/55 of the studies reported details about how they recruited their participants. Only 8/55 studies reported having randomly selected participants for their studies, although a further 18 included all of the patients who attended their clinic or stayed at the mental health unit. A non-random method of selection, e.g. consecutive patients attending a clinic on a given day was utilised by 7/55 of the studies. A high response rate is often used to judge the quality of a study, however only 24/55 of the studies reported a response rate of the individuals they invited to be involved and these ranged from 20.84% (104) to 97.23% (63). Inclusion and/or exclusion criteria were reported by 26/55 of the studies. Some studies (31, 105) had edentulism as an exclusion criterion, but few reported how many they excluded for this reason. Two studies (32, 62) only included individuals that had taken antipsychotic medication for more than two years. Main reasons stated for excluding individuals involved a diagnosis of dementia, learning disability, inability to consent to take part or aggressive behaviour. A data collection period was reported for 30/55 of the studies with the length of studies ranging from one month (25) to 18 months (106).

Table 4. Quality appraisal

| Study | Control group | Sampling method | Reported response rate % | Inclusion and Exclusion Criteria | Defined data collection period | Relevant oral health outcomes |
|---|---|---|---|---|---|---|
| Adeniyi 2011 | | Consecutive outpatients | | | October - December 2008 | DMFT, CPITN |
| Al-Dabbas 2005 | | All patients | 78.4 | **Excluded**: edentulous patients. | 1st April - 1st October 2003 | Oral hygiene |
| Al-Mobeeriek 2012 | Volunteers | Convenient sample | | **Excluded:** comorbid medical conditions and those who used drugs other than psychotropic drugs. | | DMFT components |
| Angelillo 1995 | | All patients | 94 | | February - March 1994 | Dental attendance, DMFT, CPITN |
| Arnaiz 2011 | Volunteers (health professionals and university students) with no medical history of mental illness or antipsychotics. They were matched with the patient group, and the rate of drop-out in the control group was adjusted to that of the patient group. | All patients | 85.71 | **Included:** diagnosed with schizophrenia (DSM-IV-TR) (American Psychiatric Association, 2000), have had the psychiatric condition for at least 2 years, have taken antipsychotic medication for at least 2 years, being treated as an outpatient in a day centre, be over 20 years old and have been at least 18 years old when diagnosed. | | DMFT, CPITN |
| Bertard-Gounot 2013 | | All Inpatients | 87 | **Excluded:** those with aggressive behaviour. | March-June 2006 | Oral hygiene, DMFT |
| Buunk-Werkhoven 2010 | | | | | March - June 2006 | Oral hygiene |

| | | | | | | |
|---|---|---|---|---|---|---|
| Chalmers 1998 | | | | | 1992 | Dental attendance |
| Chu 2010 | | All patients | 75.48 | | July 2006 | DMFT |
| Etlas 2012 | | Random sample | | **Included:** schizophrenia for more than 2 years, have taken antipsychotics for more than 2 years**.** **Excluded:** patients within child and youth services, those who have received periodontal therapy within the last 12 months, systemic diseases that could affect periodontal outcomes or those who have taken systemic antibiotics within the last 6 months. | | Oral hygiene, DMFT |
| Farrahi-Avval 2008 | | All patients | 20.84 | **Excluded:** negative prophylactic antibiotic coverage, medical conditions due to increased harm and those unable to give consent. | | Oral hygiene, dental attendance, DMFT, CPITN |
| Flammer 2009 | | Consecutive admissions to hospital | | | 2008 | Oral hygiene |
| Ghaffarinejad 2013 | | | | | | DMFT |
| Gopalakrishnapillai 2012 | | All patients | | **Excluded:** hospitalized in the criminal patient wing or the intensive psychiatric unit (aggressive/violent/ physically unfit/patients with suicidal tendencies), if they were unwilling to undergo the examination, or if an oral examination was otherwise contraindicated in cases such as unconscious patients in the critical care unit and those who were advised rest following sedative administration. | June-August 2008 | CPITN |
| Gurbuz 2010 | | All patients | 97.23 | **Included:** at least two functioning teeth in one sextant. **Excluded:** severe mental retardation, aggression or lack of cooperation. | | DMFT, Oral hygiene, CPITN |
| Hashimoto 2005 | Workers in the hospital | | | | | Oral hygiene, dental |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | attendance, DMFT. |
| Hede 1992 | | Random sample | 70 | | November 1988 | Oral hygiene, dental attendance |
| Hede 1995 | | Patients enrolled at the day of the examination | 82.99 | **Excluded:** patients in the psychogeriatric wards | 2 months in 1993 | Oral hygiene, dental attendance |
| Hsieh 2012 | | | | | | Oral hygiene |
| Janardhanann 2011 | Community comparison group | Stratified sampling from outpatient clinic | | **Included:** onset before age 45 | | Dental attendance |
| Jayakumar 2011 | | Convenient sample | | **Included:** those aged 50 years +, not aggressive and cooperative. Patients or their guardians willing to give consent.<br>**Excluded:** less than 50 years old, aggressive and uncooperative people, hospitalised psychiatric patients | 3 months | Oral hygiene |
| Jovanovic 2010 | | All patients | 77.5 | **Excluded:** serious somatic illness, severe disability, dementia, learning disability, aggression, uncooperative patients | March - June 2007 | Oral hygiene, dental attendance, DMFT |
| Jyoti 2012 | | | | | | DMFT |
| Kebede 2012 | | | 62.5 | **Excluded:** patients whose condition was deemed to be serious, those with alcohol or substance abuse disorders, brain injury or intellectual disability and aggression tendencies. | January to May 2011 | Oral hygiene, DMFT, CPITN |
| Kenkre 2000 | | All patients | 84.31 | | April - May 1997 | Oral hygiene, DMFT, CPITN |
| Khokhar 2011 | | | 91.18 | | 2 weeks in July 2009 | Oral hygiene, dental |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | attendance |
| Kossioni 2012 | | | | | | Oral hygiene, dental attendance |
| Krunic 2013 | | | | | | DMFT |
| Kumar 2006 | | All patients | 81.82 | **Excluded:** those with advanced dementia, those who were aggressive and uncooperative, and severely disabled patients. | January - December 2004 | Oral hygiene, DMFT, CPITN |
| Lalloo 2013 | | All patients | | | | Oral hygiene, dental attendance |
| Lewis 2001 | | All patients | 69.51 | | | DMFT, CPITN |
| Lynch 2005 | | All patients | 82 | | Aug-02 | Oral hygiene |
| McCreadie 2004 | | Convenience sample | | **Included:** those more than 18 years old with adequate English.<br>**Excluded:** those involved in another drug trial within 30 days, those who were considered unlikely to return for the follow-up. | 9 months 1999-2000 | Oral hygiene, dental attendance |
| Mirza 2001 | | | 52 | **Excluded:** those too disturbed and those with no teeth. | | Oral hygiene, dental attendance |
| Nikfarjam 2013 | | | | **Included**: patients with documented diagnosis of schizophrenia (DSM-IV-TR). | 2008 | DMFT |
| Patel 2012 | | The first 112 people attending the mental health sites | 79 | | | Dental attendance |
| Persson 2009 | | Random sampling | 78.47 | **Included:** those aged 25 years or older and have more than eight teeth | July - December 2007 | Dental attendance |
| Purandare 2010 | Outpatients and day | Convenience | | **Excluded**: those residing in a care home | 18 months | Oral hygiene, |

| | | | | | | |
|---|---|---|---|---|---|---|
| | hospital attendees from general or geriatric medicine services. | sample | | | | dental attendance |
| Rahmon 2013 | | Systematic random sampling | | **Included:** aged above 17 years. | | DMFT |
| Ramon 2003 | | Random sample of 10% of patients | | **Included**: those hospitalised for more than two years | | DMFT |
| Rehka 2002 | | | | | | Oral hygiene, CPITN |
| Sacchetto 2013 | | | | | Second half of 2011 and first half of 2012 | Oral hygiene, dental attendance |
| Sayegh 2006 | | | 95.24 | **Included:** those who had been on xerogenic medication for more than two years.<br>**Excluded:** those with less than 20 teeth | 2012 | Oral hygiene, DMFT, |
| Shah 2012 | Patients with no psychiatric disease attending the general outpatients department at the same hospital | All patients aged over 20 years attending the psychiatric outpatient department | | **Included:** aged over 20 years. | From 1st July 2009 until sample size achieved | Oral hygiene, DMFT, CPITN |
| Stiefel 1990 | | | | **Excluded:** those with heart disorders. | | Oral hygiene, dental attendance, DMFT |
| Stevens 2010 | | All patients | 41.94 | | November 2006 | Oral hygiene, dental attendance |

| | | | | | | |
|---|---|---|---|---|---|---|
| Tani 2012 | | | 95.1 | | October-December 2010 | Oral hygiene |
| Teng 2011 | | Random selection of patients from both wards | | **Included:** patients from either ward were eligible | 6 month period in 2008 | Oral hygiene, dental attendance, DMFT, CPITN |
| Thomas 1996 | | | | **Excluded:** alcohol/drug abusers and those with medical problems | | DMFT |
| UHK 2006 | | All clients invited | | | November 2005 | DMFT |
| Ujaoney 2010 | | Selected patients | 52.8 | **Excluded:** dementia, aggressive, uncooperative and severely disabled | | Oral hygiene, DMFT |
| Velasco 1997 | | Random selection of two thirds of patients | | | | DMFT, CPITN |
| Velasco-Ortego 2012 | | | 66.47 | | | DMFT |
| Wieland 2010 | | | | **Included:** those referred within the last 2 years | | Oral hygiene, dental attendance, |
| Zusman 2010 | | Random sample of 20% of patients with ID numbers ending in 5 or 7 | | **Included:** patients hospitalised for more than 1 year | 2003 | DMFT |

### 2.3.2 Oral hygiene

Oral hygiene was reported by 33 studies (Table 5). Seven studies checked whether individuals owned a toothbrush (3, 31, 66, 105, 107-109). Ownership of a toothbrush ranged from 6.7% (105) to 88.5% (31). Only one study asked participants how old the toothbrushes were and found that only 1.8% of participants had recently replaced their toothbrush (110). Frequency of tooth brushing varied across the studies. Individuals who never brushed their teeth were reported by 12 studies (59, 62, 63, 103, 104, 106, 107, 111-116) with one study finding 0% (111) all the way to 67.2% (63). From 19 studies involving 2382 people, 1102 (46.3%) brushed their teeth once a day (26, 30, 31, 34, 56, 59, 62, 103, 104, 106, 107, 110-113, 115, 117-119) but this ranged from 7.1% (112) to 93.2% (26). Only 671 (34.9%) of individuals from the 1921 involved in 15 studies brushed their teeth twice a day (3, 56, 60, 102-104, 106, 110-112, 115, 117, 119-121) but this varied from 0% (103) to 73.1% (111). Some participants rarely brushed their teeth, with 966 (35.2%) out of 2745 individuals from 16 studies confirming this (26, 59, 62, 104-106, 110, 112-117, 119, 120, 122). Those not brushing their teeth regularly was as low as 5% (106) but also as high as 88% (112). The use of mouthwash was only reported by four studies (30, 31, 111, 123) and was very low with the highest percentage being 35% (123) and the lowest being 7.7% (31). The use of dental floss or interdental cleaning aids was also very low with this outcome only being measured by seven studies (30, 34, 60, 111, 113, 121, 123) and the highest percentage only being 50% (60) and the lowest 0% (113).

Table 5. Oral hygiene

| Own a toothbrush | | | Recently replaced toothbrush | | | Brush teeth once a day | | | Brush teeth twice a day | | | Occasionally brush teeth | | | Do not brush teeth | | | Use mouthwash | | | Use dental floss/ interdental cleaning aid | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| n | N | % | n | N | % | n | N | % | n | N | % | n | N | % | n | N | % | n | N | % | n | N | % |
| 332 | 662 | 50.2 | 3 | 186 | 1.8 | 1102 | 2382 | 46.3 | 671 | 1921 | 34.9 | 966 | 2745 | 35.2 | 379 | 1795 | 21.1 | 29 | 139 | 20.9 | 51 | 261 | 19.5 |

Table 6. Dental appointment attendance

| Regular dental appointments (at least once a year) | | | Emergency dental appointments only | | | Last dental appointment <12 months | | | Last dental appointment <24 months | | | Last dental appointment >12 months | | | Last dental appointment >24 months | | | Registered with a dentist | | | Last dental appointment due to trouble with teeth | | | Last dental appointment due to check up | | | Never attended a dental appointment | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **n** | **N** | **%** | **n** | **N** | **%** | **n** | **N** | **%** | **n** | **N** | **%** | **n** | **N** | **%** | **n** | **N** | **%** | **n** | **N** | **%** | **n** | **N** | **%** | **n** | **N** | **%** | **n** | **N** | **%** |
| 392 | 686 | 57.1 | 165 | 736 | 22.4 | 629 | 1456 | 43.2 | 45 | 89 | 50.6 | 259 | 450 | 58 | 197 | 664 | 29.7 | 98 | 223 | 43.9 | 55 | 90 | 61 | 50 | 192 | 26 | 10 | 142 | 7 |

### 2.3.3 Accessing professional dental care

Seven studies reported that participants attended what the individual studies regarded as "regular dental visits" (at least once a year) (34, 104, 106, 111, 117, 120, 124) with the number ranging from 28% (106) to 77% (124). Within the National Health Service in the UK the clinically recommended maximum intervals for a dental check-up are up to 24 months for adults, but dentists will recommend a dental check-up recall interval based on their assessment of an individual's current dental health (125). The dental recall interval will vary depending on country. Those attending emergency dental visits only were reported in five studies (25, 104, 111, 113, 122), the number ranging from 7.4% (25) to 73.1% (111).

Individuals who last attended a dental appointment within the previous 12 months was reported by 13 studies (3, 31, 34, 104, 106, 110, 113, 120, 122-124, 126, 127) with attendance ranging from 12.6% (113) to 90% (123). From these 13 studies, 43.2% (629/1456) of participants had their last dental appointment within the previous 12 months. When this was extended to 24 months, one study found that half of the people they asked had visited a dentist within the previous 24 months (45/89 50.6%) (127). People having attended their last dental appointment more than 12 months ago was found for 58% (259/450) of those from six studies (34, 66, 104, 110, 121, 123) with the individual studies finding rates of 10% (123) to 85.5% (110). Overall 29.7% of people from seven studies had attended their last dental appointment more than 24 months ago (31, 34, 56, 104, 122, 124, 128), but individual studies rates were lower and ranged from 5% (34) to 51.8% (128).

Being registered with a dentist was checked by three studies with less than half of the individuals questioned in each study confirming that they were registered with a dentist with an average of 43.9% (3, 106, 127). Some people had never attended a dental appointment but the two studies which included this outcome

found that the numbers in their populations were very low finding 6.9% (104) and 7.5% (121).

The 'reason for the last dental appointment' was only provided by two studies, one of which found that 61% of participants had attended due to trouble with their teeth, and only 33% had attended due to a regular dental check-up (30), whilst another found that 19.6% had also attended for a check-up (104).

### 2.3.4 Oral state – Decayed Missing Filled Teeth (DMFT)

Some studies had edentulism (having no natural teeth) as an exclusion criterion. Of the studies included in the review, 23 recorded the number of individuals who were edentulous and found 18.8% (742/3951) were edentulous (24-26, 30-32, 54, 59, 63, 105, 106, 108-111, 113, 117, 120, 124, 127-130).

The DMFT measure was used by 31 studies (24-27, 32, 34, 52-54, 57, 59, 62, 63, 103, 104, 108, 111, 112, 115, 116, 122, 129-138). High scores on the DMFT indicate poor oral health: more decayed, more missing, and more filled teeth. A DMFT score provided by 27 studies concerning a total of 6143 individuals overall was M 15.98, SD 10.45. The decayed component of the DMFT measure was M 4.25, SD 5.37 when combining data from 21 studies with 3782 people. Missing teeth were prevalent; this component of the DMFT was recorded for 3923 people from 22 studies M 8.46, SD 10.54. The number of filled teeth varied between studies but an overall score on this component of the DMFT for 21 studies involving 3782 individuals was M 4.8, SD 8.47.

Table 7. Decayed Missing Filled Teeth (DMFT)

| DMFT | | | Decayed | | | Missing | | | Filled | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| N | M | SD | N | M | SD | N | M | SD | N | M | SD |
| 6143 | 15.98 | 10.45 | 3782 | 4.25 | 5.37 | 3923 | 8.46 | 10.54 | 3782 | 4.8 | 8.47 |

### 2.3.5 Treatment Needs – Community Periodontal Index of Treatment Needs (CPITN)

The CPITN measure was reported by 14 studies. Very few individuals (209/2855, 7.32%) had no need for treatment in these 14 studies (CPITN 0) (24-26, 32, 57, 63, 104, 108, 112, 114, 116, 122, 129, 139). Oral hygiene instruction was required by 13.3% (379/2855) of people with serious mental illness as bleeding was present on probing (CPITN 1). Calculus was visible on the surface of teeth in 36.4% (1039/2855) of individuals (CPITN 2). Shallow pockets were present in 25.1% (641/2550) of those with serious mental illness as were deep pockets in 18% (445/2471) of those with serious mental illness. Two studies combined those with shallow and deep pockets and found 37% (113/305) would require treatment for shallow or deep pockets (57, 122).

Table 8. Community Periodontal Index of Treatment Needs (CPITN)

| Healthy | | | Bleeding | | | Calculus | | | Shallow pockets | | | Pockets | | | Deep pockets | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 0 | | | 1 | | | 2 | | | 3 | | | 3&4 | | | 4 | | |
| n | N | % | n | N | % | n | N | % | n | N | % | n | N | % | n | N | % |
| 209 | 2855 | 0.73 | 379 | 2855 | 13.3 | 1039 | 2855 | 36.4 | 641 | 2550 | 25.1 | 113 | 305 | 37 | 445 | 2471 | 18 |

### 2.3.6 Studies with a control group from the general population

There were 14 studies that compared the oral health of people with serious mental illness with a control group from the general population (32, 34, 102, 103, 106, 110, 111, 114-116, 126, 130, 134, 138). Data were analysed using RevMan5 (140). The odds ratio with a 95% confidence interval was chosen for binary data as it has statistical advantages relating to its sampling distribution and included studies involving a cross sectional design. For continuous data the mean difference (MD) was used, again with a 95% confidence interval as the data being analysed from the studies used the same scale for each outcome (DMFT, or CPITN). A random effects model was used as significant heterogeneity was found for the majority of analyses.

Edentulism was more prevalent in the mental health population but the difference was not to a statistically significant extent (OR 4.91, 95% CI 0.59 to 40.52, p = 0.14; participants = 843; studies = 5; $I^2$ = 88%). Recently replacing a toothbrush was only reported by one study, but it was found that those in the general population group were far more likely to have recently replaced their toothbrush with 3/186 in the mental health population and 146/186 in the general population group having done so (OR 0.00, 95% CI 0.00 to 0.01; participants = 372; studies = 1; $I^2$ = 0%). No significant differences were found for brushing teeth once a day (OR 0.99, 95% CI 0.29 to 3.34, p = 0.98; participants = 907; studies = 6; $I^2$ = 88%) or twice a day (OR 0.32, 95% CI 0.09 to 1.08, p = 0.07; participants = 1079; studies = 6; $I^2$ = 92%) or only brushing teeth occasionally (OR 5.06, 95% CI 0.03 to 947.99, p = 0.54; participants = 452; studies = 2; $I^2$ = 96%). However, individuals with a serious mental illness were found to be more likely never to brush their teeth (OR 39.00, 95% CI 4.87 to 312.00, p = 0.0006; participants = 117; studies = 2; $I^2$ = 0%) than the general population. No difference was found for the use of mouthwash (OR 1.07, 95% CI 0.17 to 6.59, p = 0.94; participants = 37; studies = 1; $I^2$ = 0%) but those with serious mental illness were less likely to use dental floss or interdental cleaning aids (OR 0.30, 95% CI 0.11 to 0.87, p = 0.03; participants = 105; studies = 2; $I^2$ = 0%).

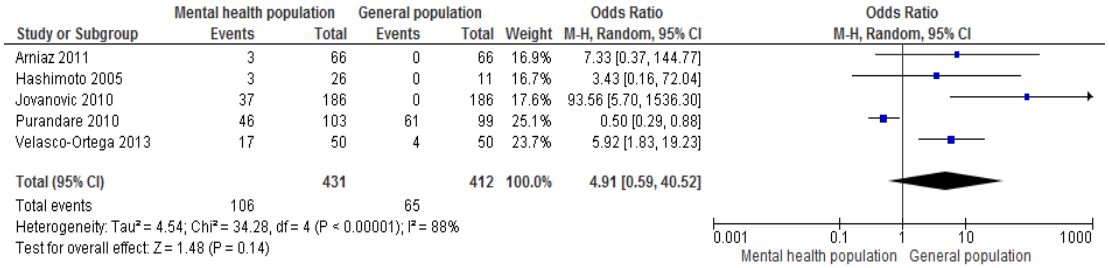


Figure 2. Edentulous

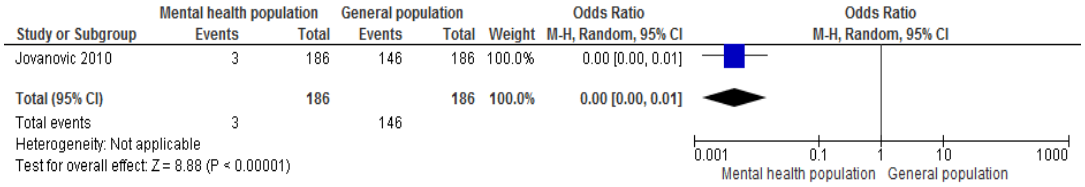


Figure 3. Recently replaced toothbrush

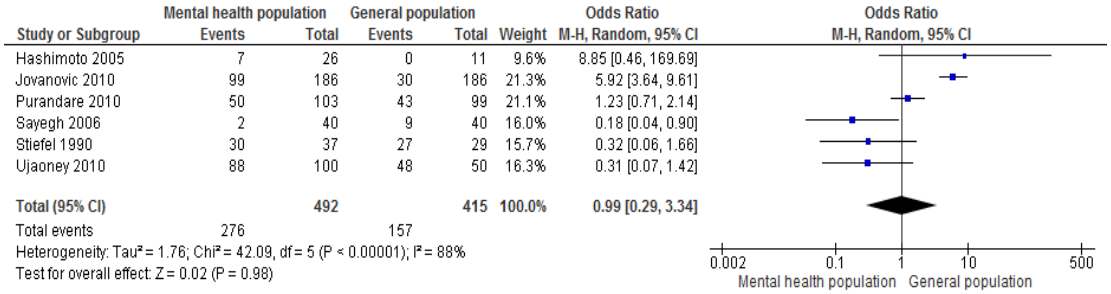


Figure 4. Brush teeth at least once a day

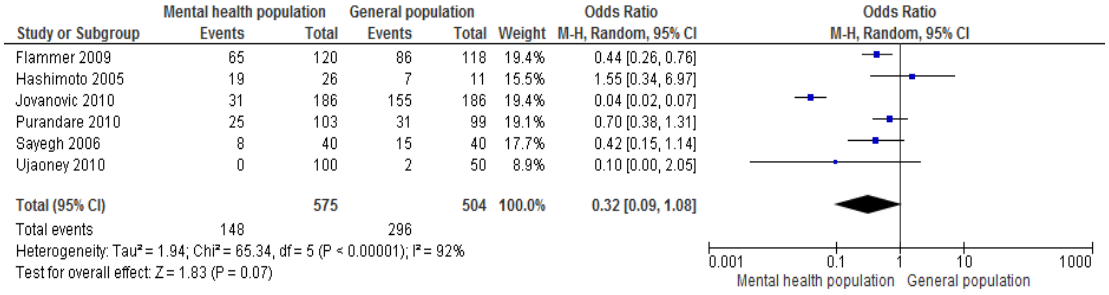


Figure 5. Brush teeth at least twice a day

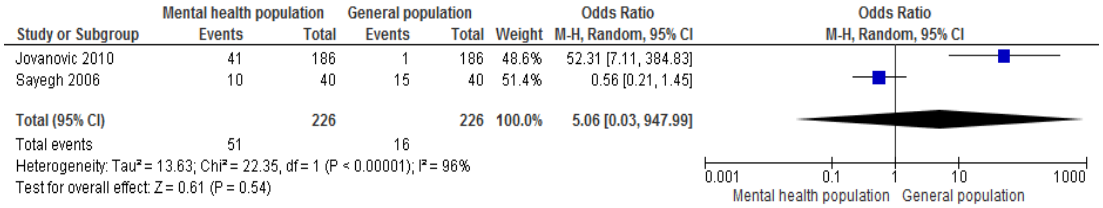


Figure 6. Occasionally brush teeth

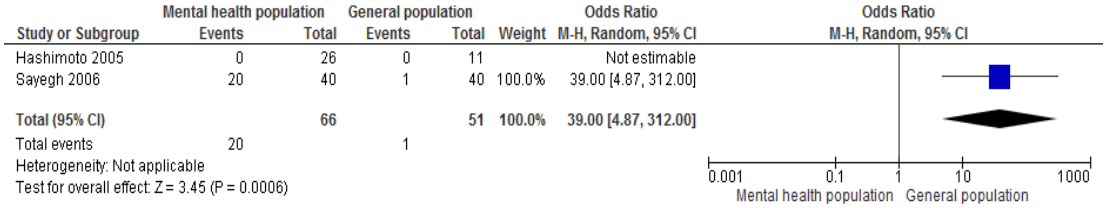


Figure 7. Do not brush teeth

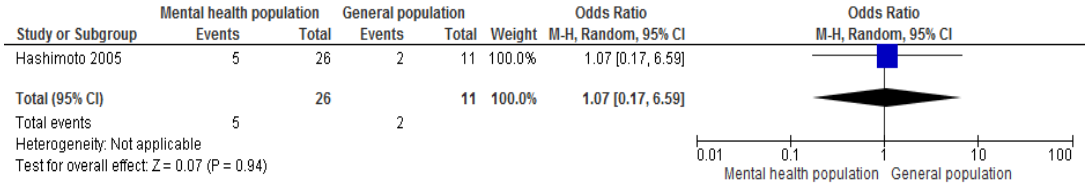


Figure 8. Use mouthwash

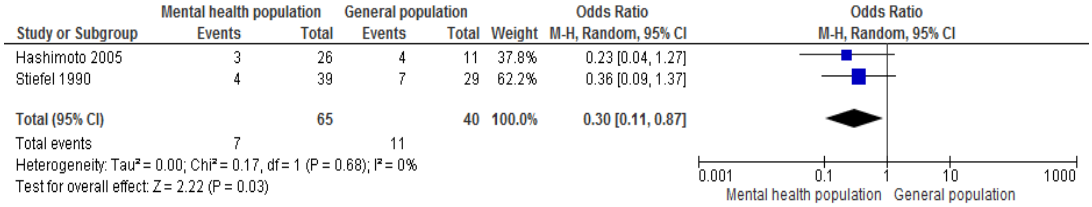


Figure 9. Use dental floss/dental cleaning aid

No differences were found for visits to a dentist within the previous 12 months (OR 0.44, 95% CI 0.04 to 4.43, p = 0.49; participants = 951; studies = 4; $I^2$ = 98%), but data from one study indicated that individuals with serious mental illness were more likely to have last visited a dentist over 12 months ago (OR 103.64, 95% CI 48.64 to 220.86, p < 0.00001; participants = 372; studies = 1; $I^2$ = 0%). There was no difference between the mental health groups and general population group when attending regular dental appointments (once a year) (OR 1.18, 95% CI 0.69 to 2.02, p = 0.56; participants = 268; studies = 2; $I^2$ = 0%) or

being registered with a dentist (OR 1.33, 95% CI 0.77 to 2.33, p = 0.31; participants = 202; studies = 1; $I^2$ = 0%).

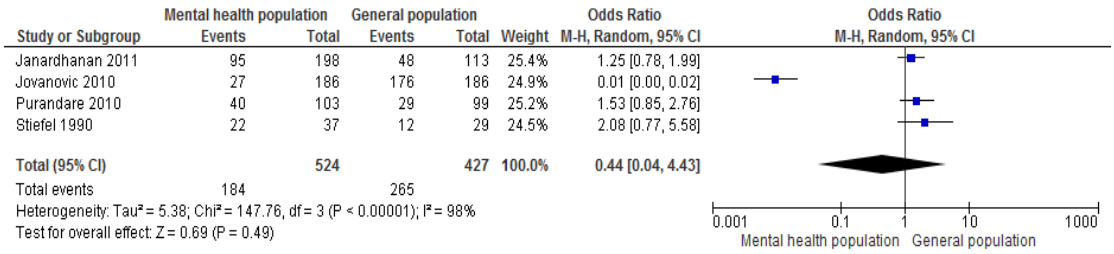


Figure 10. Dental appointment <12 months

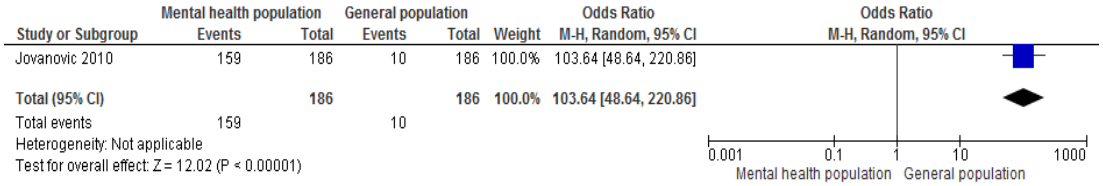


Figure 11. Dental appointment >12 months

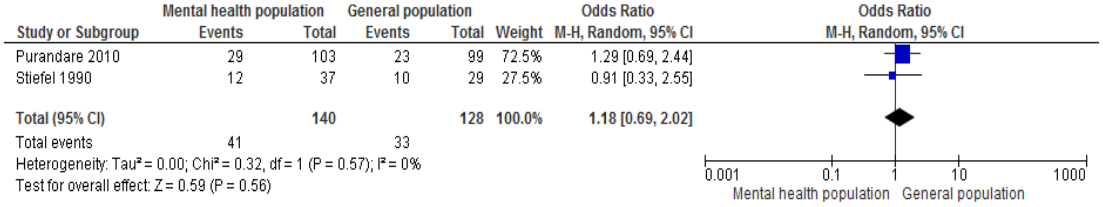


Figure 12. Attend regular dental appointments (at least once a year)

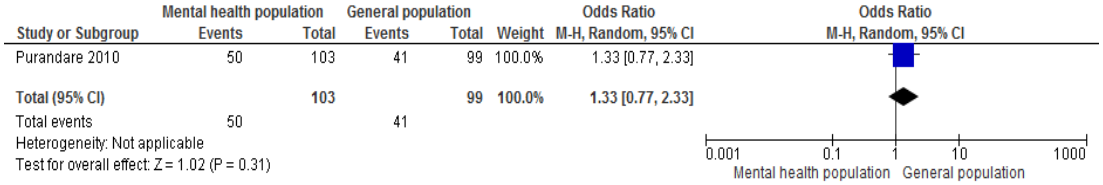


Figure 13. Registered with a dentist

The number of Decayed Missing and Filled Teeth (DMFT) was measured by seven studies with a general population comparison group (32, 103, 111, 115, 132, 134, 138). Overall the DMFT was found to be significantly higher in the clinical population, indicating the oral health of those with serious mental illness was in a poorer state than individuals in the control group from the general population

(MD 5.16, 95% CI 2.27 to 8.04, p = 0.0005; participants = 1117; studies = 6; $I^2$ = 98%). A greater number of decayed teeth (MD 2.95, 95% CI 2.07 to 3.84, p < 0.00001; participants = 1052; studies = 7; $I^2$ = 89%) and missing teeth (MD 4.41, 95% CI 1.68 to 7.13, p = 0.002; participants = 1052; studies = 7; $I^2$ = 98%) were found for the clinical population. Filled teeth were significantly more prevalent in the general population (MD -2.94, 95% CI -4.95 to -0.93, p = 0.004; participants = 1052; studies = 7; $I^2$ = 98%).

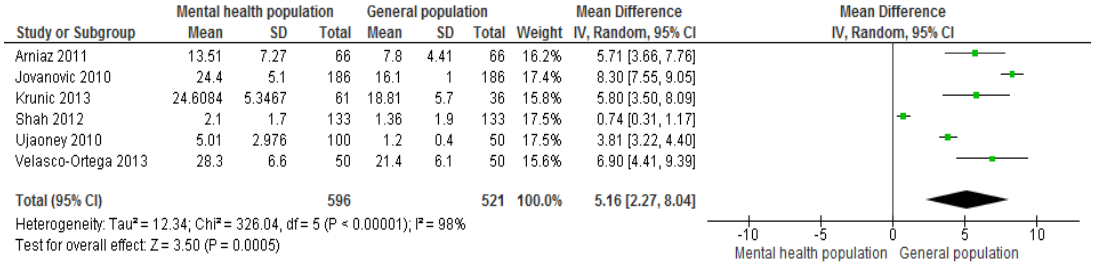


Figure 14. DMFT

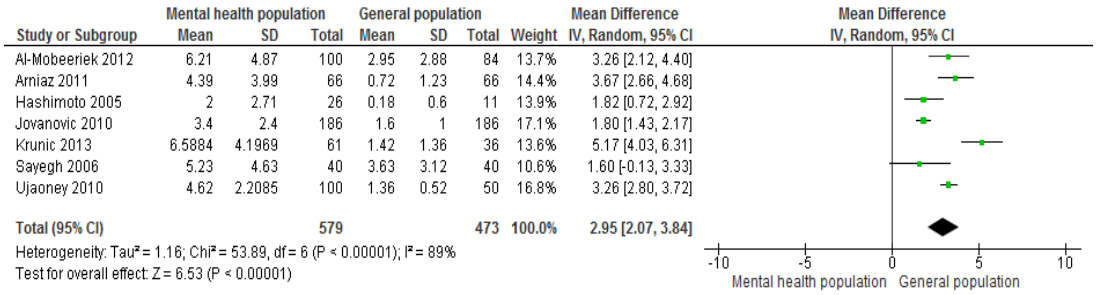


Figure 15. Decayed teeth

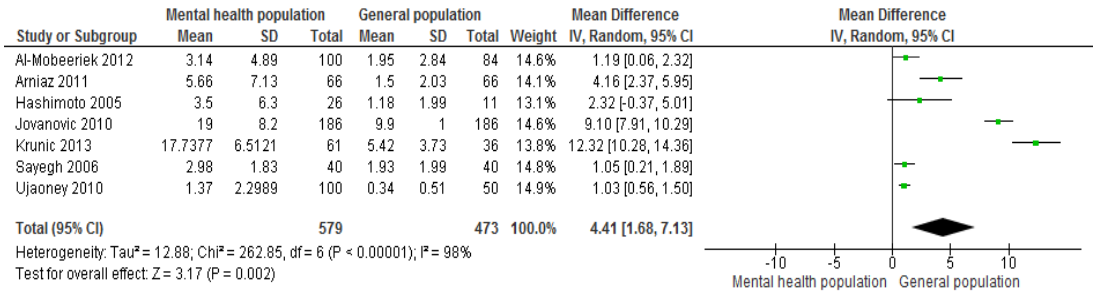


Figure 16. Missing teeth

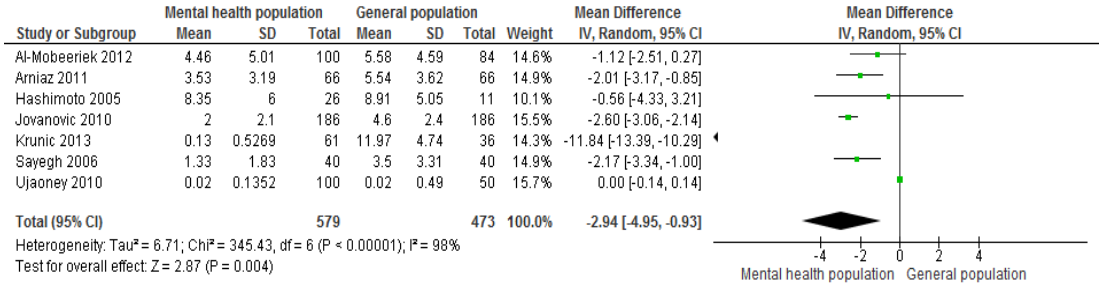


Figure 17. Filled teeth

The CPITN was measured by three studies with a general population control group (32, 114, 116). More of the general population comparison group had healthy periodontal tissue (CPITN 0) than those with serious mental illness (OR 0.16, 95% CI 0.09 to 0.28, p < 0.00001; participants = 877; studies = 3; $I^2$ = 0%). There was not a great difference in the numbers of those experiencing bleeding (CPITN 1) (OR 0.61, 95% CI 0.32 to 1.16, p = 0.13; participants = 877; studies = 3; $I^2$ = 32%) or having visible calculus (CPITN 2) (OR 0.67, 95% CI 0.32 to 1.40, p = 0.29; participants = 877; studies = 3; $I^2$ = 83%). Individuals with serious mental illness were significantly more likely to have shallow pockets (CPITN 3) (OR 2.34, 95% CI 1.24 to 4.42, p = 0.009; participants = 877; studies = 3; $I^2$ = 69%) and deep pockets (CPITN 4) in their teeth (OR 2.86, 95% CI 1.66 to 4.92, p = 0.0002; participants = 877; studies = 3; $I^2$ = 0%).

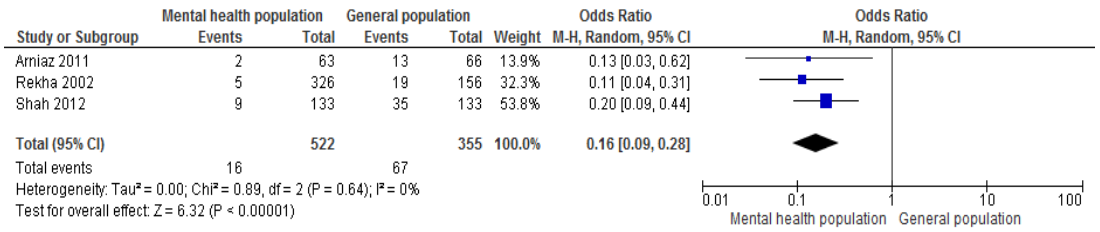


Figure 18. CPITN

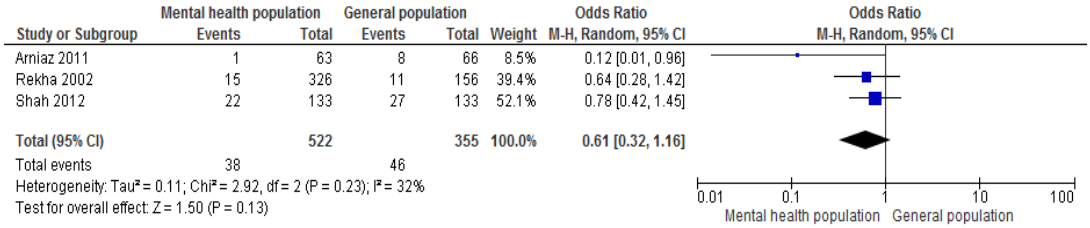


Figure 19. CPITN1 (bleeding)

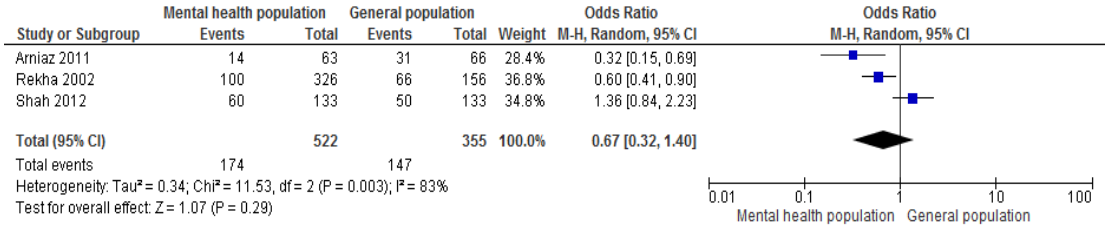


Figure 20. CPITN2 (visible calculus)

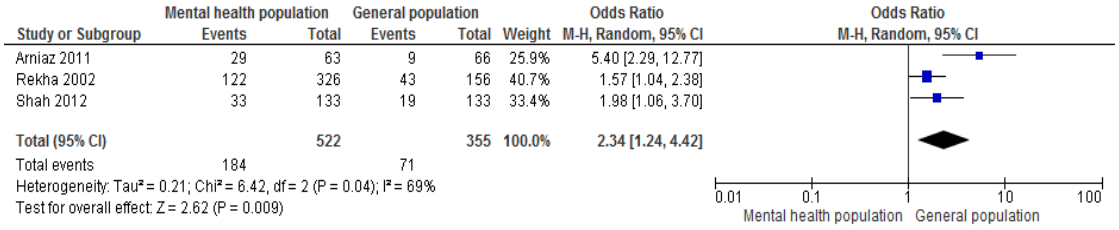


Figure 21. CPITN3 (shallow pockets)

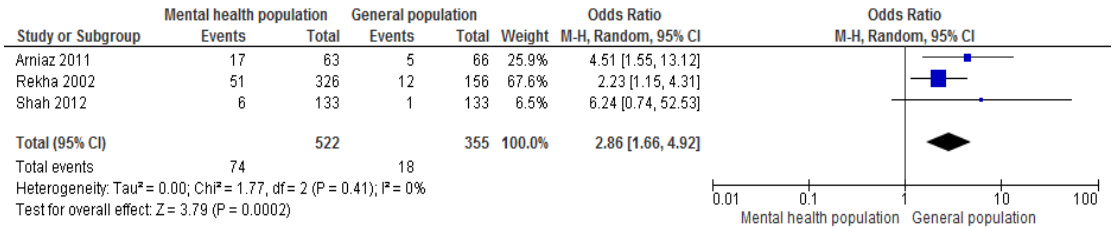


Figure 22. CPITN4 (deep pockets)

## 2.4 Discussion

There were wide variations in findings among studies in this review. Studies also varied in quality, but there was a considerable amount of data from relevant outcomes that was not reported in a useable way (e.g. means reported but not standard deviation). If sufficient data had been available, a sensitivity analysis

excluding studies judged to be of low quality was planned, but there were so few high quality studies, this was not attempted. Only 32/55 studies published details regarding sampling methods with 18 including all patients, eight randomly selecting individuals to be involved and seven reported using a non-random method of selection e.g. consecutive patients attending a clinic on a given day. A high response rate is often used to judge the quality of a study, however only 20/55 of the studies reported a response rate of the individuals they invited to be involved. Reported response rates ranged from 21% to 97.23%. Inclusion and/or exclusion criteria were reported by 26 studies. Some studies (31, 105) had edentulism as an exclusion criterion, but few reported how many they excluded for this reason. Two studies (32, 62) only included individuals that had taken antipsychotic medication for more than two years. Main reasons stated for excluding individuals involved a diagnosis of dementia, learning disability, inability to consent to take part or aggressive behaviour. A data collection period was reported for 30 studies with the length of studies ranging from one month (25) to 18 months (106).

Access to dental care may differ depending on setting and this may go some way to explain why such variations were seen in the studies included in this review. Participants included in the studies conducted in outpatient settings would have had wider access to dental care than those in inpatient settings. Some studies conducted in inpatient settings reported having a dedicated dental clinic on site (63, 120), others reported that individuals were able to make appointments with local dentists if and when required (3) but some studies reported that patients in the hospitals had no access to professional dental care (30, 107). Oral hygiene products like dental floss or mouthwash may not always be available to individuals in certain inpatient mental health units (e.g. mouthwash sometimes contains alcohol).

Different countries may have different culturally specific oral hygiene methods. Some of the studies reported different methods of maintaining oral hygiene

other than using a toothbrush including the use of a finger with toothpaste or toothpowder by 21.6% of individuals in one study in India (107). A study in Greece also found that whilst 62.5% of individuals used a toothbrush and toothpaste, 6.3% used a toothbrush and water, 25% rinsed with water, 3.1% used a finger with salt and 3.1% used a finger with water to clean their teeth (113). Another study reported that 34.6% of participants had healthy oral hygiene practices but did not state what they were (116). Therefore, using a toothbrush may not always be the norm so this outcome may not be appropriate for all of the studies included in this review. Moreover, there is no universally recognised definition of what a routine dental check-up consists of, or how often it should take place. In most countries standard practice is a dental recall interval of between six months and two years, despite there being no evidence to support the benefit of this practice (141).

Although the diagnoses of type of mental illness were known for the majority of participants, the severity of illness was not. Previous studies indicated that individuals who were in recovery were more likely to seek treatment more frequently and create a greater demand for services than those with more severe psychiatric problems (40).

It has been suggested that the high prevalence of missing teeth may be interpreted to mean that the people with serious mental illness who receive dental treatment are more likely to have teeth extracted rather receiving conservative treatment. This may be related to the perceived difficulty in patient management or to an individual's unwillingness or inability to accept the care either for dental anxiety or because they are too ill (25). Dentists may extract teeth rather than provide restorative treatment as it may be quicker and cheaper to do so. The total absence of oral hygiene maintenance in some individuals could be attributed to a physical inability or poor mental capacity to perform oral hygiene procedures (107).

### 2.4.1 Conclusion

Despite variations in the reporting of data and overall quality of studies, this review adds to our knowledge of the oral health of those with serious mental illness. Unlike other recent reviews, this review explored the oral hygiene practice of people with serious mental illness and reported this alongside the uptake of professional dental care services. These data show that the majority of people with serious mental illness do not practice good oral hygiene. Findings indicate that those with serious mental illness are less likely to brush their teeth than the general population, but for those who do brush their teeth there is no great difference in frequency compared to the general population. There were few studies with a comparison group to add weight to the finding from individual studies that people with serious mental illness infrequently attend dental appointments; the only difference highlighted in this review was that people with serious mental illness were more likely not to have seen a dentist for a longer period of time than the general population. The DMFT findings support previous systematic reviews, showing that those with mental illness are likely to have more decayed teeth, and more missing teeth, but fewer filled teeth, than the general population. The CPITN showed that few people with serious mental illness had healthy periodontal tissue and therefore did not require any dental treatment. Oral hygiene instruction was required due to bleeding gums on probing during the dental examination, and calculus was visible on the surface of teeth in a third of individuals. Shallow pockets were present in a quarter of those examined and only slightly fewer had deep pockets in their teeth and would therefore require complex dental treatment.

Overall findings from this review indicate that the oral health of people with serious mental illness is poor and also highlights the lack of professional dental care received by this population. People with serious mental illness are less likely to brush their teeth at all than the general population. This leaves them at greater risk for tooth decay, so it is not surprising that they also had more teeth that were decayed or had already been extracted, and also required more

complex dental treatment than the general population. Oral health self-care and engagement with professional dental services for those with serious mental illness needs to improve. The reasons why people with serious mental illness infrequently attend regular dental appointments should be explored further to allow steps to be taken to improve the quality of, and access to, care.

The next chapter will explore the knowledge of and attitudes towards oral health in mental health populations from the service user, mental health and dental professionals' perspective.

## CHAPTER THREE. Knowledge and attitudes regarding oral health in populations with serious mental illness: Service users, and mental health and dental professionals' perspectives

The previous chapter focused on the prevalence of poor oral health and hygiene practices as well as professional dental treatment received by people with serious mental illness. The research has highlighted that people with serious mental illness have poor oral health, are more likely to neglect their oral hygiene, and are less likely to receive professional dental treatment than the general population.

### 3.1 Introduction

The physical health of people with serious mental illness will only improve if there is a collaborative approach across primary and secondary health care services (142). Mental health care settings are integral to this and mental health nurses in particular can have an important role to play in improving the overall health care of their patients (30, 143-145). However, the UK Department of Health 2006 guidelines for supporting the physical health needs of people with serious mental illness does not mention the role of the mental health nurses in assisting their patients with their oral health care (146). Some mental health nurses do however provide this care to their patients, but there are discrepancies in this practice.

The purpose of this chapter is to explore perspectives surrounding oral health in those with serious mental illness from the service user, mental health professional and dental professional points of view from the existing literature. Factors influencing the prevalence of poor oral health and hygiene practices of those with serious mental illness will be discussed in the context of a narrative review with an aim of gaining insight into the extent to which service users, mental health professionals and dental professionals are aware that people with mental illness are likely to have problems with their oral health, reasons for this and possible solutions.

### 3.2 Methods

#### 3.2.1 Search Strategy

MEDLINE, PsycINFO, CINAHL and EMBASE were searched using the following terms in December 2011: ((chronic$ or severe$ or serious$ or persistent$) adj (mental$ or psych$) adj (disorder$ or ill$)) or (schizo$ or psychotic$ or psychosis or psychoses) and ((tooth or teeth or dent* or (oral adj2 health) or (oral adj2 hygiene)). No language or date restrictions were used. The search was repeated on a regular basis to identify new studies with the final search in December 2014.

#### 3.2.2 Procedure

In order to be included in this review studies had to report data regarding the oral health of people with mental illness from the service user, and/or mental health professional and/or dental professionals' perspective. Studies that did not meet these criteria were excluded. Citations from the electronic search were screened. From the 1507 citations identified, 24 papers covered this topic and were included in the review. Study quality was not assessed due to the varied study designs included; data was extracted from published letters or short reports with very limited methodological details making an appropriate appraisal not possible.

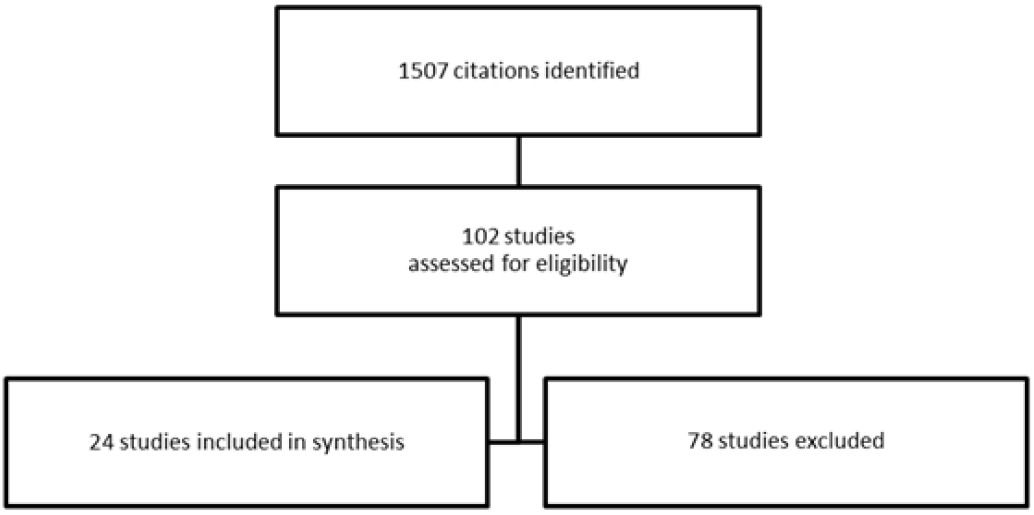


Figure 23. Flow diagram

Themes regarding awareness or misconceptions of the importance of oral health and hygiene behaviour, role of the mental health professional in oral health care

assistance, and barriers for people with mental illness accessing dental services were identified from the literature which is discussed under the sub-headings below.

### 3.3 Results

#### 3.3.1 Awareness or misconceptions of the importance of oral health and hygiene behaviour

The importance of oral health is well known. The vast majority of mental health service users in one study agreed that having healthy teeth was important with respect to well-being, social relations and personal appearance (117). Tooth brushing was recognised as being important for oral health, although only half actually brushed their teeth twice a day and they were largely unaware of the possible oral health related side effects of the medication they were taking for their mental illness. Service users felt that their prescribed medication that caused dry mouth was associated with a feeling that teeth were deteriorating and regular tooth brushing was not enough to stop caries from developing (147, 148). The neglect of oral hygiene could be attributed to a lack of awareness, as it has also been found that individuals who rated their oral health as good had periodontal pockets (space that develops between the gum and tooth) when examined by a dentist (122). The current evidence points to the majority of service users not identifying the necessity of routine dental check-ups as integral to good oral health and a tendency only to visit a dentist when experiencing a dental emergency (25, 30, 113, 122), they also often had greater unmet dental treatment needs than the general population (82).

Not all service users believe their poor oral health is a result of their mental illness in adulthood (117, 149). Many had neglected their oral health from childhood, so caries in later life was almost inevitable. One possible explanation is that people with serious mental illness are more likely to evaluate good oral health as a lack of pain rather than evidence of good oral health involving an absence of caries, plaque etc. (149). It should also be noted that not all people with serious mental illness neglect their oral hygiene, indeed one study found

that overzealous brushing caused as many problems as neglecting to brush at all (65, 147). Although most research has concluded that people with serious mental illness rarely visit the dentist, a study conducted in the USA comparing the number of dental appointments in the last year between people with schizophrenia and the general population found no difference (126).

### 3.3.2 Role of the mental health professional in oral health care assistance

Oral health care assistance provided by mental health nurses varies, with some service users receiving a lot of advice, reminders or assistance (99), and others receiving none (25, 113). Some service users were grateful for assistance or advice from their mental health nurse, others saw it as not their place and became resentful of reminders to brush their teeth, reduce consumption of sugary foods, or attend appointments (147). In one study, service users indicated that they often discussed oral health concerns with community mental health centre staff and felt that they helped with oral health care by reminding them to brush their teeth or making dental appointments, helping to complete forms, accompanying them to appointments, and interpreting procedures at the dental visit (149). Nearly all patients in another study (95%) reported that they felt that mental health staff considered their oral health as important as they did, and supported them in visiting the dentist (123).

The extent to which physical health care is seen as part of the role of mental health staff varies. Mental health nurses in an Australian study indicated that they thought that *identifying* oral health needs was a part of their role, but they did not always consider that *assisting with* oral health was part of their role (123). The nurses also reported feeling as though dentists expected them to prompt patients about their oral health on a daily basis and often communicated with the mental health staff member, rather than the patient directly during dental appointments. This supports the notion that mental health nurses do not always see physical health care as part of their role; indeed prompting patients on a daily basis would considerably add to their workload, and if oral health is

not seen as a priority by the mental health professionals they may be unwilling to carry out what is being requested of them by the dental professionals.

There are differences in the oral health care provided by mental health professionals to their patients between countries but also policy within the same country can vary between institutions. In a cross-sectional survey of 136 nurses in Nigeria, nearly all of the nurses reported that they assisted service users with cleaning their teeth with either a toothbrush, toothpaste, gauze, mouthwash or a warm saline mouth bath, and most also assisted service users with looking after their artificial teeth (150). An Internet-based survey of 643 mental health nurses in Australia found that they rarely provided oral health advice to service users (151); and another study in the Netherlands was similar in that most of the nursing staff failed to perform oral hygiene procedures for service users who neglected to brush their teeth (83). It is not always standard clinical practice to ask patients about their oral health which may be a barrier to helping mental health nurses meet the oral health needs of their service users (123). The mental health nurses in this study also indicated that more pressing clinical priorities often prevented them from discussing oral health with service users. All of the staff interviewed could identify some of their own patients with poor oral health and thought that improving their oral health could also improve their self-esteem and have a positive effect on both their mental and physical health. The nurses interviewed did not express a great awareness of oral side effects of antipsychotic medication e.g. dry mouth. If nurses are not aware that medication like antipsychotics can cause dry mouth they will be unable to assist their patients with their oral health effectively. They also reported some negative experiences when attending dental appointments with patients to support them including dental staff sometimes became frustrated with patients who experienced delusions or if they were anxious, dentists often used complex language that made it difficult for patients to understand what was being asked of them, overloading patients with too much information and demonstrating little understanding of the patient's cognitive deficits. If nurses had received

appropriate training with assisting their patients with their oral health they would be more aware of possible problems and be able to support them at dental appointments.

Some deficits in the provision of oral health care in individuals with serious mental disorders have been identified in some mental health settings, and specific services to combat this have been implemented (123). In one case, as part of an evaluation of a new dental partnership between a mental health service and dental service, focus groups and surveys were undertaken with 43 community-based mental health staff. Oral health was only seen as a priority in recovery planning for patients by a quarter of the mental health staff; most of them had referred one of their patients to a dentist in the previous two years and the majority of those patients actually attended the appointment. Again, the level of proficiency felt by staff to deliver this care was low with less than half feeling confident that they could identify the oral health care needs of their patients and many wanting to improve on these skills and receive additional training.

A study conducted in Hong Kong found that most of the nurses claimed they provided oral hygiene advice to their service users (137) and some assisted service users with brushing their teeth at least once a day. The relationship between diet and oral health was discussed by some of the nurses but it was very rare for them to arrange a regular dental check-up for their service users once a year and most claimed they would only arrange a dental check-up for service users if they had a dental problem.

### 3.3.3 Barriers for people with mental illness accessing dental services

A previous negative experience at the dentist has been reported by service users as a significant barrier to attending dental appointments (65, 84, 147). Individuals have stated feeling unable to discuss their mental health with their dentist, due to a concern about how they may be judged and how this may affect the treatment they receive due to stigma surrounding mental illness (149). One

study reported a combination of physical restraint and/or medication or anaesthetising patients was used for the dental examinations in a psychiatric hospital for the study (85). Not all service users have had positive experiences and the fear of visiting dentists may also be ascribed to pain and/or extraction. It has been suggested that dentists are more likely to extract teeth from people with serious mental illness, rather than provide restorative treatment [26]. Individuals may be left with few teeth and require dentures. One study that interviewed people with a serious mental illness who had had all their teeth extracted found that they experienced considerable regret for not having looked after their teeth earlier in life [14] and many reported that they had never been taught how to care for their teeth properly, as well as having little motivation for oral hygiene due to their mental illness.

Dental anxiety is common in the general population with 12% of respondents to the UK Adult Dental Health Survey meeting criteria for extreme dental anxiety (152). Fear of going to the dentist is another reason that contributes to dental avoidance among people with serious mental illness, with one study finding that service users reported fear of dental treatment prevented them from going (117). However, when people with serious mental illness did visit a dentist, some experienced positive outcomes. A survey of individuals with serious mental illness who had visited a new dental partnership service set up in Australia revealed very positive feedback about the visit to the dentist (123). Most service users thought that the dentist had given them helpful instructions and nearly all then followed the advice. Service users felt as though the dentists explained things to them in a way that they could understand, and all reported that they thought they were treated with respect. All of the patients agreed that it had been worthwhile going to the dentist, and nearly all said they would attend further treatment. The main reason given for not attending follow-up appointments was due to deteriorating mental health. When an individual's mental health deteriorates inpatient treatment is sometimes necessary, and studies have identified that tooth brushing frequency may decrease during

inpatient stays, not only due to the severity of mental illness but also due to not having access to a toothbrush (113).

Financial reasons have also been proposed as a reason for neglecting oral health care (34). Professional dental treatment can be expensive, with restorative treatment often costing more than a tooth extraction. Therefore, even if individuals express a desire for treatment it may be beyond their means, and many service users have reported being unclear about what treatments may be available without additional charge (e.g. on the National Health Service or Medicaid) (149). This was also corroborated with mental health nurses' reports that many of their patients were not aware of free access to public dentistry that was available to them (123). Furthermore, many people with serious mental illness have such serious financial constraints that not only do they have to reject dental treatment, but also cut back on oral hygiene products like toothpaste (149). This issue is also prevalent in the UK general population with 26% of those who responded to the latest UK Adult Dental Health Survey (2009) reporting that in the past, the type of dental treatment they have chosen to have had been affected by how much the treatment cost and 19% had delayed dental treatment due to cost (152).

A lack of time and a lack of training has been cited as a barrier to mental health professionals assisting service users with oral health care (128). The likelihood of mental health nurses providing physical health care, including elements like oral health to their patients has been found to be related to their own attitudes of confidence in and likelihood of delivering the physical health care, whether they had recently received training in physical health care, and their level of overall mental health nursing experience (153). This suggests that if mental health nurses received more training and support in providing oral health care, and received regular training updates, this may in turn increase their confidence in providing the care and increase the likelihood of them actually assisting their patients with the oral health care needs. In a survey of 168 mental health nurses

in London, the majority delivered physical health care to their patients, but almost all were of the opinion that they should have received more training in physical health care in order to do so effectively (154). The level of training in physical health care for mental health nurses varies; one study found that the majority of nurses they surveyed had received additional oral health care training after they had qualified, and nearly all thought that they should receive regular training on meeting the oral health care needs of their patients (150). Most of these nurses also thought that a dentist should be attached to the psychiatric hospital for patients' oral health needs to be met sufficiently (150).

Wieland et al. recognised that people with serious mental illness often experience barriers to dental treatment including being unable to afford expensive dental treatment and patients not always seeing dental care as important (123). Findings from this study show that the mental health nurses thought that patients were less likely to care for their teeth than the general population and most thought that patients were quite likely to cancel dental appointments. The nurses cited patient lifestyle choices as well as the impact of negative mental health symptoms on whether or not patients performed adequate oral hygiene.

In one study, most of the nurses agreed that individuals with serious mental illness were likely to have higher prevalence of dental problems than the general population (150). The main explanations for the higher prevalence rates provided by the nurses were that: patients were often sedated for long periods of time, there was a lack of care provided by family members when individuals were not hospitalised, symptoms of the mental illness prevented adequate oral hygiene behaviour, limited access to a dentist and a lack of oral hygiene advice given to service users. Side effects of psychiatric medication, financial reasons and an inability to perform adequate oral hygiene behaviour were also identified. Most of the nurses stated that their service users had complained about their oral health (e.g. toothache), with some of the nurses providing advice on tooth

brushing or recommending referral to a dentist. Some patients did not cooperate with the care, and did not have access to a toothbrush or toothpaste or refused oral care. An inadequate number of nurses, lack of time, perceived lack of benefit to patients, and that patients have more pressing problems were also reported as reasons why oral health care was not always given to service users.

To determine how dental care was provided in one psychiatric hospital in the Netherlands, 61 nurses were interviewed to examine their role in the prevention and diagnosis of dental problems in their patients (83). Findings revealed that some had not received any training for providing oral health care but they reported that they wanted more information about oral health care. In another study in Hong Kong, most of the nurses surveyed claimed they had never received any oral health training, and for the few that had received oral health training, it had not been updated (137). Few of the nurses felt they actually had sufficient knowledge to deliver oral health care to their patients, and in line with findings in other studies, an interest in receiving updated oral health care training was expressed.

Dentists who had been involved in a new dental service established as a partnership between a mental health service and dental service thought that people with serious mental illness are less likely to take adequate care of their teeth, with half being of the opinion that individuals with a mental illness do not realise the importance of caring for their teeth as much as the general population (123). Most of the dentists also felt that people with a mental illness frequently cancelled appointments and they expressed frustration with patients not attending appointments or not finishing a course of dental treatment. Some were of the opinion that people with a mental illness would not follow dental advice given and felt as though they may not understand instructions provided to them. Dental professionals mentioned that having a member of staff from the mental health service present during appointments to support the patient was useful, and also to then help the patients with oral health advice and follow

treatment plans. The same study identified that mental health nurses didn't always see oral health care as part of their role, so expectations of individuals is unclear and this may explain why there is such a disparity between the oral health care assistance that people with serious mental illness receive. Dental professionals also highlighted concerns regarding people with mental illness and effects that medications prescribed for their mental illness may have on their oral health. High prevalence of smoking and poor dietary choices by people with serious mental illness were also raised as a concern by the dentists.

It is not only mental health professionals who feel as though they lack training: dentists have also revealed that they do not feel they had received adequate training regarding the dental needs of individuals with severe mental illness (128). Specific issues with treating this population were identified including difficulties relating to symptoms of mental illness and many would attend for emergency treatment only rather than regular check-ups which may prevent more serious oral health problems in the longer term. In addition, the dentists also mentioned that people with a serious mental illness would often not complete a course of treatment, request a general anaesthetic for planned treatment, and may want to leave frequently to smoke cigarettes during treatment.

### 3.4 Conclusions

Individuals with serious mental illness are more likely to have poor oral health due to neglecting oral hygiene and not attending regular dental appointments. Previous negative experiences at dental appointments or general dental anxiety may prevent them from seeking help until they experience a dental emergency. The role of the mental health professional in the oral health care of their patients varies. There was an indication that identifying oral health needs was a part of their role, but providing assistance with oral health was not. Mental health nurses themselves appeared to be unclear about what their role involved so until all parties are aware of what their expectations and responsibilities are, improvement is unlikely. The majority of service users reported benefiting from

support from mental health nurses, even though nurses tend to report feeling unconfident and inadequately trained to provide this care. There is little clarity of the role of mental health professionals regarding oral health in mental health from service users, dental professionals and the mental health professionals themselves. Dental professionals often sought help from mental health professionals; this sometimes appeared to be perceived by the mental health nurses as outside of their role and dentists also reported having received a lack of training to treat people with serious mental illness.

Oral health advice may be beneficial to individuals with a mental illness. Service users could be prompted about tooth brushing and attendance at dental appointments. Whilst receiving inpatient treatment, a toothbrush and toothpaste should be made available. It would appear that continuing training in oral health care could help to increase a feeling of competence and confidence for the nurses and result in them being more willing to engage in caring for the oral health of their patients. Mental health nursing practice should involve acknowledging the importance of physical health in mental health and the roles and responsibilities of mental health nurses to improve health care outcomes. Dentists would also benefit from more training regarding treating people with a serious mental illness. They were also positive about service users receiving support from mental health nurses; if a mental health nurse attended dental appointments with service users many of the frustrations experienced by dentists treating individuals from this population may be prevented.

The next chapter will focus on evaluating randomised studies of oral health interventions for people with serious mental illness.

# CHAPTER FOUR. A systematic review of interventions for improving the oral health of people with serious mental illness

## 4.1 Introduction

Previous research discussed in earlier chapters has indicated that people with serious mental illness have poor oral health. This chapter will explore interventions that have been designed and implemented to attempt to improve the oral health of people with serious mental illness. Recent Cochrane reviews (3, 4) evaluated the extent to which trials have evaluated the guidelines set out by the British Society for Disability and Oral Health (2) which recommend that everyone with serious mental illness should have their oral health monitored and should receive oral health advice as part of standard care. These reviews found no existing randomised controlled trials (RCTs) of oral health advice, or oral health monitoring for people with serious mental illness. However, there may be oral health interventions for this population that do not fall under the heading of advice or monitoring (and may be effective). Furthermore, there may be non-RCTs that may not have been included in the Cochrane reviews. RCTs are however considered to be the most reliable source of evidence for the effectiveness of interventions because the strict protocols that are followed during an RCT reduce the risk of bias in the results and findings produced are therefore more likely to be closer to the true effect than from other research methods (155). The gold standard research methodology for evaluating evidence for the effectiveness of interventions is seen as a systematic review (156). Therefore, a systematic review of RCTs of oral health interventions for people with serious mental illness was undertaken.

## 4.2 Objective

To conduct a systematic review to determine the effectiveness of oral health interventions for people with serious mental illness.

## 4.3 Method

### 4.3.1 Search Strategy

The search strategy was compiled of oral health and mental health keywords. One search that would include all topics to be covered in the thesis was carried out, citations from all the databases were imported into Endnote, duplicates were removed and citations were separated into themes for later use in individual chapters. The original search was carried out in January 2012 with the assistance of a librarian and regularly updated by HJ with the final top-up search in December 2014 to identify recently published studies. MEDLINE, PsycINFO, CINAHL and EMBASE were searched using the following terms: ((chronic$ or severe$ or serious$ or persistent$) adj (mental$ or psych$) adj (disorder$ or ill$)) or (schizo$ or psychotic$ or psychosis or psychoses) and ((tooth or teeth or dent* or (oral adj2 health) or (oral adj2 hygiene)). No language or date restrictions were used.

### 4.3.2 Inclusion criteria and exclusion criteria

RCTs that compared an oral health intervention with a control for people with serious mental illness were included. An oral health intervention was defined as any procedure that was implemented with the intention of improving the oral health of the studies' participants. Studies conducted in any healthcare setting involving people of any age or gender who were diagnosed with serious mental illness that was either author defined or cited standardised diagnostic criteria (e.g. DSM-IV / ICD-10) were included. Studies of any design that were not RCTs were excluded from the review.

### 4.3.3 Outcomes

Outcomes of interest were those concerning:

- Oral health (any measure of oral health e.g. DMFT)
- Adverse events
- Leaving the study early (drop out)

- Mental state (any measure of current mental state e.g. CPI)

### 4.3.4 Quality assessment

The quality of studies included in the review were appraised using the criteria from the Cochrane Collaboration risk of bias tool (157). This included evaluation of: random sequence generation, allocation, blinding, incomplete outcome data, selective reporting, and other potential sources of bias.

## 4.4 Results

### 4.4.1 Results of the search

The search identified 1507 citations. HJ screened titles and abstracts against the eligibility criteria and 17 studies were identified for further inspection of the full papers. Following inspection of these papers, four studies met the inclusion criteria and were subsequently included in this review.

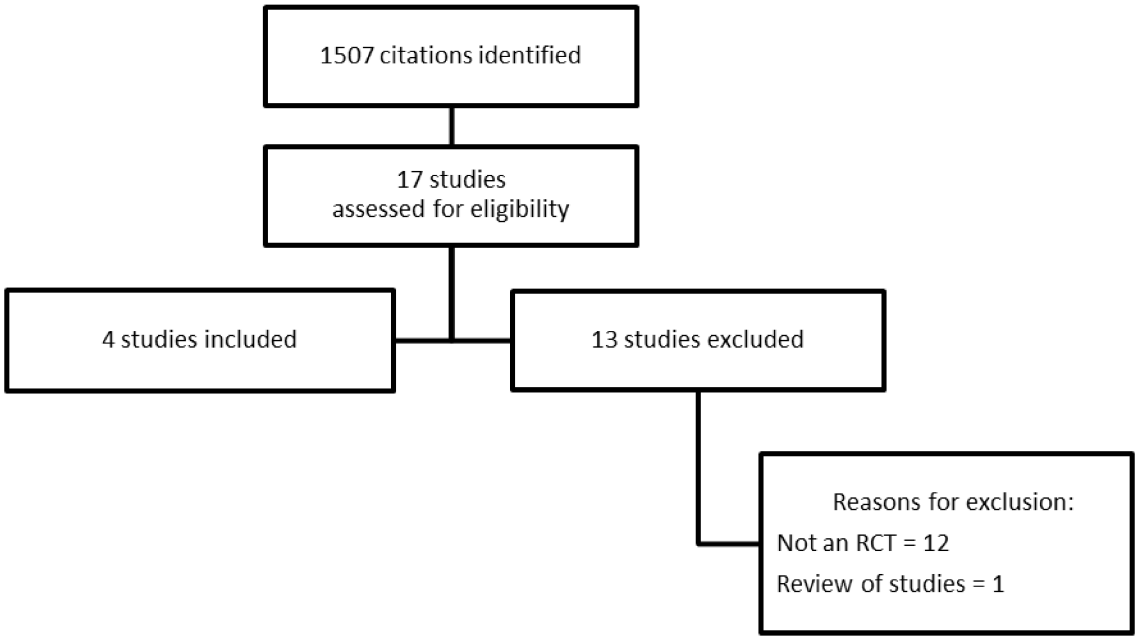


Figure 24. PRISMA

### 4.4.2 Included studies

The included studies involved different interventions and most measured different outcomes, thus it was not appropriate to perform a meta-analysis (158). The Cochrane Handbook also states that "*a common criticism of meta-analyses is that they 'combine apples with oranges'. If studies are clinically*

*diverse then a meta-analysis may be meaningless, and genuine differences in effects may be obscured. A particularly important type of diversity is in the comparisons being made by the primary studies. Often it is nonsensical to combine all included studies in a single meta-analysis: sometimes there is a mix of comparisons of different treatments with different comparators, each combination of which may need to be considered separately. Further, it is important not to combine outcomes that are too diverse*" (159) (p.246). Data were also poorly reported, so findings from the studies will therefore be presented narratively (and are also summarised in Table 9).

Two studies were conducted in the USA (41, 58), one in Korea (90), and the other in Poland (98). Sample sizes were relatively small: 50 (58), 60 (41), 73 (90), and 100 (98) participants respectively. Follow-ups were also short at four weeks (58), eight weeks (41), ten weeks (98), and twelve weeks (90), thus the long term effects of the oral health interventions for serious mental illness cannot be ascertained.

Table 9. Study characteristics of included studies

| Study | Participants | Intervention | Comparison | Outcomes | Findings |
|---|---|---|---|---|---|
| Almomani 2006 (58) | **Country:** USA.<br>**n:** 50 (42 (84%) completed).<br>Intervention n=25, comparison n=25.<br>**Age**: 19-61 years of age.<br>**Gender:** 18 males, 32 females.<br>**Diagnosis:** Serious mental illness (schizophrenia, bipolar disorder, depression), diagnosis was determined by self-report and confirmed by medical records.<br>**Inclusion criteria:** Minimum of one gradable tooth in each sextant (no crown, no frank caries, and no broken tooth or restoration).<br>**Exclusion criteria**: Obvious periodontal disease (e.g. mobile | **Intervention:** Dental education + oral hygiene instructions + mechanical toothbrush + tooth brushing reminder system. **Description:** Dental education (15 mins) involved discussing effects of chronic mental illness on oral health, advantages of good oral hygiene, and disadvantages of bad oral hygiene. Participants were given pamphlets explaining the impact of mental illness and psychotropic medications on oral health and the correct way to brush teeth using a mechanical toothbrush.<br>Oral hygiene instructions (10 mins) consisted of being given a mechanical toothbrush (Crest Spin | **Comparison:** Mechanical toothbrush alone. | **Time points:** Four weeks.<br>**Outcomes:**<br>• Plaque scores (Modified Quigley-Hein Plaque Index) (160). | The intervention group improved significantly more than the comparison group ($F = 5.32$, $P = 0.026$, $\eta^2 = 0.1$). |

| | | | | | |
|---|---|---|---|---|---|
| | teeth, severe gingival hyperplasia, heavy calculus), participants with orthodontic appliances, pregnancy, mental retardation, severe hearing or visual problems, major neurological ill-ness, people with dementia, people with guardians or those unable to comply with the study protocol, individuals who do not have a mobile and/or regular phone, or those who are currently using a mechanical toothbrush. | Brush Pro) and instructed to brush twice a day for two minutes. The participant was observed brushing their teeth and given feedback.<br>Tooth brushing reminders consisted of a small plastic box and specially designed reminder post-it-notes with 60 pages. Participants were instructed to put a note in the box each time they brushed their teeth. Participants were telephoned once a week to provide positive feedback and reinforce the study instructions. | | | |
| Almomani 2009 (41) | **Country:** USA.<br>**n:** 60 (56 (93%) completed). Intervention n=30, comparison n=30.<br>**Age:** 22-62 years of age.<br>**Gender:** 27 male, 33 female. | **Intervention:** Motivational interviewing + oral health education.<br>**Description:** Motivational interviewing session (15-20 mins) focused on exploring advantages and disadvantages, | **Comparison:** Oral health education alone. | **Time points**: Four weeks, eight weeks.<br>**Outcomes**:<br>• Plaque scores (Modified Quigley-Hein Plaque Index) (160).<br>• Oral health knowledge (15- | The intervention group had significantly lower plaque scores than the comparison group at week 8 ($p < 0.01$). Oral health knowledge scores were significantly higher in |

| | | | | | |
|---|---|---|---|---|---|
| | **Diagnosis**: Severe mental illness (schizophrenia, bipolar disorder, and depression).<br>**Inclusion criteria**: At least one gradable tooth in each sextant.<br>**Exclusion criteria**: Obvious periodontal disease, orthodontic appliances, significant physical or cognitive disabilities, not having access to a phone, or currently using a mechanical toothbrush. | motivation, confidence, and personal values related to daily tooth brushing and oral health.<br>Oral health education session provided information about the effects of severe mental illness on oral health, the advantages of good oral hygiene, and the disadvantages of bad oral hygiene.<br>All participants received two pamphlets summarizing the information from the education session, instruction in using a mechanical toothbrush (Crest Spin Brush Pro), a reminder system, and weekly telephone calls (for four weeks). | | item Oral Health Knowledge questionnaire).<br>• Self-regulation Treatment Self-regulation Questionnaire (TSRQ) (161).<br>• Adverse events. | the intervention group at week 4 and 8 ($p < 0.01$).<br>For self-regulation there was a statistically significant main effect of intervention<br>Which favoured the intervention group ($F = 5.17$, $p < 0.027$, $\eta 2 = 0.078$).<br>No adverse events were reported. |
| Mun 2014 (90) | **Country**: Korea<br>**n:** 88 (73 (83%) completed).<br>Intervention n=23, comparison 1 n=22, | **Intervention:** Oral healthcare education + two professional tooth brushing practice sessions + oral healthcare | **Comparison:**<br>1) Oral healthcare education + oral healthcare brochure.<br>2) Oral healthcare | **Time points**: Four weeks, eight weeks, 12 weeks.<br>**Outcomes:**<br>• Plaque Index - Patient Hygiene Performance index | For the plaque index, significant differences were found between the intervention and comparison groups (P |

| | | | | | |
|---|---|---|---|---|---|
| | comparison 2 n=28.<br>**Age:** 20-65 years.<br>**Gender:** 36 male, 37 female.<br>**Diagnosis:** 89% schizophrenia, 1.4% schizoaffective disorder, 2.7% bipolar disorder, 4.1% depression, 2.7% other.<br>**Inclusion criteria:** At least one normal tooth in each sextant.<br>**Exclusion criteria:** Significant pathological manifestations in the oral tissues, fixed orthodontics, pregnancy, unable to communicate, visual or auditory disabilities, unable to complete all follow-up assessments, those with alcohol addiction or those who could not participate in inpatient care. | brochure. **Description:** The oral healthcare education session involved a 10 minute interactive video which focused on knowledge of oral health, attitudes about oral health and self-management of behavioural changes. The brochure contained the same information in written format.<br>The professional tooth brushing practice sessions involved a demonstration of correct tooth brushing method. | brochure. | (PHP index) (162)<br>•Stimulated salivary flow.<br>• Acid production of oral bacteria and the lactobacillus test.<br>•Leaving the study early. | = 0.036). No significant differences in subjective oral dryness scores or acid production were found. |

| | | | | | |
|---|---|---|---|---|---|
| Tanasiewicz 2011 (98) | **Country**: Poland<br>**n**: 100. Intervention n=50, comparison n=50.<br>**Age**: 37.5 ± 0.5 years<br>**Diagnosis:** Schizophrenia<br>**Exclusion criteria:** Individuals who did not sign consent forms, those unwilling to take part, taking anti-hypertension calcium channel blockers, anti-epileptic drugs, contraceptives, after chemotherapy or patients suffering from disorders like leukaemia and other white-blood cell system disorders, taking antibiotics any time during the last three months, legally incapacitated, without teeth or with removable dentures, hospitalised for less than two weeks. | **Intervention:** Professional hygienic training.<br>**Description:** Professional hygienic training involved verbal presentation and training on correct teeth cleaning, a check of their ability to conduct correct cleaning, and providing leaflets on oral hygiene that included descriptions of proper tooth brushing techniques together with toothbrushes and toothpaste. | **Comparison:** No hygienic training | **Time points:** 10 weeks.<br>**Outcomes:**<br>• DMFT (decayed, missing, filled and total teeth) (163).<br>• OHI (oral hygiene) (164).<br>• API (Approximal Plaque Indices) (165). | Patients undergoing treatment with classical neuroleptics should be taken under particular care, as the effectiveness of dental hygienic activities in that group, including hygienic training for the oral cavity, was lower than in the group which was treated with atypical neuroleptics. |

### 4.4.3 Quality assessment

The risk of bias in the included studies was overall unclear (Table 10.). No study provided appropriate detail about the conduct of their studies, one study had six out of six quality assessment points deemed not to have sufficient evidence to make a judgement as to the risk of bias involved (90), and a second had five of the six points judged to be unclear [12]. Only two studies (41, 58) reported using a random number table to assign participants to groups which was conducted by one of the members of the study team who was not directly involved in the study. Blinding of participants and healthcare providers in interventions such as these is difficult as it is obvious whether participants receive an education intervention or not, but it is possible to blind outcome assessors. One study used an examiner blind to intervention (58), and another reported using a blinded validity check by the gold standard examiner on five participants per group (10 participants total) who had been selected at random at week eight which revealed high reliability (r=0.976) between examiners (41). Intention to treat analyses were not used where participants did not complete the study (41, 58, 90), and two studies had reported that they were sponsored by tooth brush companies (41, 58).

Table 10. Quality assessment

| Study | Random sequence generation | Allocation | Blinding | Incomplete outcome data | Selective reporting | Other potential sources of bias |
|---|---|---|---|---|---|---|
| Almomani 2006 (58) | **Low risk:** Random numbers table used to assign participants to groups. | **Low risk:** Randomisation and treatment assignment were performed by a member of the study team who not involved in data collection. | **Low risk:** Unable to blind personnel or participants to an education intervention, but reported to be examiner blind. | **Unclear risk:** Incomplete outcome data were described but not addressed. There was no intention to treat analysis. | **Unclear risk**: All outcomes reported in methods reported in results but protocol not available. | **Unclear risk:** The study was supported by Proctor and Gamble and participants were provided with a Crest Spin Brush Pro mechanical toothbrush. |
| Almomani 2009 (41) | **Low risk:** Random number table used to assign participants to groups. | **Low risk:** Randomisation and treatment assignment were performed by a member of the study staff who was not involved in collecting the data. | **Unclear risk:** Unable to blind personnel or participants to an education intervention, but blinding of outcome assessors not reported. Blinded validity check on 10 randomly selected participants (5 per group) at week eight by the gold standard examiner. | **Unclear risk:** Incomplete outcome data were described but not addressed. There was no intention to treat analysis. | **Unclear risk**: All outcomes reported in methods reported in results but protocol not available. | **Unclear risk:** The study was supported by Proctor and Gamble and participants were provided with a Crest Spin Brush Pro mechanical toothbrush. |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | High reliability between examiners was found. | | | |
| Mun 2014 (90) | **Unclear risk:** Reported that participants were given serial numbers consecutively and then randomly allocated to three groups separately, but no further information. | **Unclear risk:** Insufficient information. | **Unclear risk:** Unable to blind personnel or participants to an education intervention, but blinding of outcome assessors not reported. | **Unclear risk:** Incomplete outcome data were described but not addressed. There was no intention to treat analysis. | **Unclear risk**: All outcomes reported in methods reported in results but protocol not available. | **Unclear risk:** No sources of bias identified. |
| Tanasiewicz 2011 (98) | **Unclear risk:** Reported as randomised but no further information. | **Unclear risk:** Insufficient information. | **Unclear risk:** Unable to blind personnel or participants to an education intervention, but blinding of outcome assessors not reported. | **Low risk:** No missing data. | **Unclear risk:** All outcomes reported in methods reported in results but protocol not available. Full result not reported for all outcomes. | **Unclear risk:** No sources of bias identified. |

### 4.4.4 Participants

Studies (41, 58, 90) involved participants with “severe mental illness” including diagnoses of schizophrenia, bipolar disorder, and depression, and the other study (98) only involved those diagnosed with schizophrenia. The studies did not report using any formal diagnostic criteria for participants' diagnoses before including them, but one study that recruited participants from a community support program confirmed diagnosis by accessing participants’ medical records after requesting permission to do so (58). Participants were recruited from a ‘community program’ (41, 58), ‘mental health centre’ and ‘psychiatric hospital’ (90) and a ‘Psychiatric Clinical Ward’ (98), so a formal diagnosis is highly likely. All studies included both male and female participants, but one did not report the number of each (98). For three of the studies inclusion criteria specified that participants were required to have at least one gradable tooth and the remaining study did not report inclusion criteria as such, but did report that participants would be excluded if they were without teeth (98).

### 4.4.5 Interventions

All of the interventions involved an oral hygiene education component in which correct tooth brushing was demonstrated. They also all involved written instructions regarding correct tooth brushing being provided to participants. One study compared dental education plus oral hygiene instructions plus mechanical toothbrush plus a tooth brushing reminder system vs. mechanical toothbrush alone (58), another involved motivational interviewing plus oral health education vs. oral health education alone (41), oral healthcare education plus two professional tooth brushing practice sessions plus and oral healthcare brochure vs. oral healthcare education plus an oral healthcare brochure vs. an oral healthcare brochure alone (90), and the final study compared professional hygienic training vs. no hygienic training (98). All participants in two studies were provided with tooth brushes (41, 58), and only those in the intervention group were provided with toothbrushes in another study (98).

### 4.4.6 Outcomes

Times varied considerably across studies. One study measured outcomes at four weeks (58), another measured at four weeks and eight weeks (41), measurements at ten weeks were taken for one study (98), and the final study took measurements at four weeks, eight weeks and twelve weeks post-intervention (90).

#### 4.4.6.1 Oral health

The Modified Quigley-Hein Plaque Index was used to score plaque accumulation on the buccal and lingual surfaces of Ramfjords teeth index (166) for two studies (41, 58). This method involves examining opposite quadrants of an individual's dentition, and the authors reported that if any of these teeth were missing or were not gradable, the closest tooth was graded. The study that compared dental education plus oral hygiene instructions plus mechanical toothbrush plus a tooth brushing reminder system versus using a mechanical toothbrush alone found that plaque scores significantly improved for both groups over the four weeks (both $p<0.001$), but the group who received the education and instructions as well as the mechanical toothbrush improved by a slightly greater margin than those who were only given the toothbrush ($P = 0.026$) (58). Results from the other study showed that the plaque scores of those who received motivational interviewing reduced between baseline and four weeks ($p<0.01$) as well as between four weeks to eight weeks ($p<0.01$), and those who received education only reduced from baseline to four weeks ($p<0.01$), but did not change between four and eight weeks ($p>0.05$) (41). Participants in the motivational interviewing group had significantly less plaque at week eight than the education only group ($p<0.01$).

The Patient Hygiene Performance index (162) was used to assess the plaque index in just one of the studies (90). One tooth per sextant was used to measure the dental plaque. The adjacent tooth was measured if the tooth that had been selected was unavailable for measurement. For the intervention group and both of the comparison groups, dental plaque significantly decreased after each

session ($p<0.0001$) and significant differences were found between the groups ($p=0.036$) with the biggest change of 50.1% from baseline being seen in the group who received an oral healthcare education session plus an oral healthcare brochure, a 41.9% change was seen in the group who also received two tooth brushing instruction sessions, and the group of participants who only received an oral healthcare brochure had a plaque score change from baseline to twelve weeks of 30.1%.

Xerostomia and saliva production was measured by one study (90). No significant differences in dry mouth were found between the intervention group or comparison groups at any time point; however, increased saliva production was seen in all three groups of participants after four sessions. Subjective oral dryness scores significantly decreased for the intervention group and both comparison groups, but no significant differences were seen between the intervention or control groups. No significant differences were found for the oral bacteria acid production test.

A 15-item Oral Health Knowledge questionnaire was developed for one of the studies (41). A panel of three clinicians with expertise in survey methods had evaluated the questionnaire for face validity, and then it was piloted on five people with severe mental illness to make sure that participants would be able to understand the questions. The questionnaire was found to have good internal consistency (Cronbach's alpha coefficient = 0.78). Oral health knowledge was found to improve significantly for both the intervention and control groups from baseline to four weeks ($p<0.01$), but did not improve between four and eight weeks. Oral health knowledge was found to be significantly higher in the group which had received motivational interviewing alongside education than the education alone group at both week four and week eight ($p<0.01$).

The DMFT (71) was used in one study (98) to measure the prevalence of dental caries and the number of teeth in the mouth. The score is expressed as the total number of teeth that are determined to be decayed (D), missing (M), or filled (F)

in an individual. The scores can range from 0 to 28 or 0 to 32, depending on whether the third molars are included in the scoring as this is optional. All of the elements of the DMFT were assessed to be less than satisfactory for the hygienic training group in comparison to the control group. Significance levels for the ten week follow up were not reported in the study so cannot be reproduced.

The Treatment Self-regulation Questionnaire (TSRQ) (161) concerning oral hygiene was used to assess each participant's self-regulation for brushing his/her teeth regularly for one study (41). The TSRQ measures the degree to which people perform a healthy behaviour. When an external source of motivation has been internalized to a degree where its presence is no longer required to initiate or maintain the behaviour, this is known as introjected motivation. Introjected motivation significantly increased in both groups across the eight weeks ($p<0.002$). For external and autonomous regulation where behaviours are controlled by external forces like incentives or to avoid a punishment, there was a significant increase in scores over the eight weeks for both groups, but there were no significant differences between the intervention or control groups (41).

The degree of the hygiene of the oral cavity for participants in the largest study was assessed with the use of the Approximal Plaque Index (API) (98). In this study the participants were divided into separate groups depending on what medication they received and then randomised within those groups to receive the intervention or control. The full results from this analysis were not presented, but it was reported that the API scores for participants treated with classical neuroleptics in the intervention group decreased from 63% (0.37 SD) to 44% (0.31 SD) over the 10 week trial. Scores for participants treated with classical neuroleptics in the control group decreased from 90% (0.21 SD) to 82% (0.29 SD), which is still very high. Those treated with atypical neuroleptics who received the intervention, their API scores decreased from 73% (0.30 SD) to 60% (0.32 SD) and participants in the control group did not decrease from baseline at all during the 10 week follow up 89% (0.24 SD) and 89% (0.24 SD). This indicates

that the hygiene training did seem to make a difference for the majority of participants, but the significance was not reported.

The Oral Hygiene Index (OHI) (164) was also used to assess the state of oral hygiene and the effectiveness of the hygiene training that could improve oral health (98). The index contains scales for both plaque and dental calculus. OHI plaque scores decreased for participants in both groups and the calculus scores increased for participants in both groups, apart from those who were prescribed classical neuroleptics and did not receive hygienic training where it decreased but was not significant.

#### 4.4.6.2 Oral health related outcomes

An evaluation questionnaire was used after one of the interventions in a study to assess participants' satisfaction with the intervention and opinions about the mechanical toothbrush with which they were provided (58). The evaluation consisted of seven questions with answers on a 5 point scale of 'never,' 'rarely,' 'sometimes,' 'most of the time,' 'always'. The questions covered whether the participant felt that the oral hygienist and dentist were well-prepared to treat them, whether the dental education was helpful, was the program boring, or was it fun, whether they had learned things to help them improve their oral hygiene, whether they had enjoyed the oral hygiene audio-visual demonstrations and if they thought the post-it-notes were a good reminder to brush their teeth twice a day. There was also space to write the three things that the participants liked and did not like about the intervention and the mechanical toothbrush. The evaluation found that 95% of the participants felt as though they had learned new information that had helped to improve their oral hygiene, 92.9% indicated that they thought the oral health promotion program was fun and was not boring and 95% found the reminder post-it-notes were a helpful reminder for them to brush their teeth. The mechanical toothbrush was well received with 95% of participants stating that it made their teeth feel cleaner than a manual toothbrush and 71.4% reported that they thought it made their teeth whiter. Only 23.8% of participants felt that the mechanical toothbrush was easier to use

than a manual toothbrush, but this may be explained by three of the participants' particular dislikes about the toothbrush as one was unable to reach their back teeth as the toothbrush head was too big, and two participants thought that the handle of the brush was big and heavy.

#### 4.4.6.3 Adverse events

No adverse events were reported in one study (41), and the remaining three did not address this outcome (58, 90, 98).

#### 4.4.6.4 Leaving the study early

Eight participants (16%) left one of the studies early, five from the intervention group and three from the control, due to moving away from the area or hospitalisation, but not related to the intervention (58). In another of the studies, four (7%) participants left early. Three participants from the Motivational Interviewing group were lost to follow up; one at week four and two at week eight. One participant from the Education only group was lost to follow up at week eight (41). There were fifteen people (18%) who left from the study involving three intervention groups, six from the group that only received an oral healthcare brochure, six left from the group that also received an oral healthcare education session and three people left from the group that also received two tooth brushing technique sessions (90). This outcome was not addressed by one of the studies, but it is not clear whether that is because no participants left the study early or it was simply not reported (98).

#### 4.4.6.5 Mental state

No study reported having assessed participants' mental state throughout their respective studies. It is therefore unclear how unwell the participants were at any time during the studies and whether the interventions had any effect on the participants' mental health.

### 4.5 Discussion

There is limited evidence to support interventions in this important aspect of patient care. There were only four relevant studies identified, and the overall

quality of the studies was quite low. Due to the variations in the interventions and outcomes in the studies it is hard to reach clear conclusions from the data. The inclusion criteria were intended to be relatively broad to ensure that relevant studies were identified as this is an under researched area and all available data is needed. No meta-analysis was possible, however some important elements of the successful oral health interventions have been identified from the studies which are discussed below.

Oral hygiene education to motivate behavioural change should be given to individuals with serious mental illness. Educating people with serious mental illness about proper tooth brushing techniques can lead to improvement in oral health and hygiene practices; one study found that the positive effects of these interventions began to decrease after a month (90). This indicates that these types of interventions may only have a short term benefit, suggesting that ongoing tooth brushing reminders and educational sessions are needed.

The study that involved motivational interviewing, although it had a very small sample size, does provide some evidence to suggest that motivational interviewing for oral health would be of benefit to those with serious mental illness, at least in the short term (41). The study only followed up participants for eight weeks, so any long term benefits are unknown. A significant improvement in oral health knowledge was also indicated in this study which could be attributed to an increase in motivation as a result of the oral health education.

Being shown how to brush teeth effectively significantly improved oral health in three studies (58, 90, 98). Rewards for brushing teeth (118), motivational interviewing (41) and receiving a new toothbrush alongside oral health education (3, 58) have also been shown to be effective interventions.

Another study found that those in the control group who did not receive any hygiene training still had a significant decrease in plaque values which may indicate that even the examination that was conducted for the trial may have

resulted in a higher awareness of oral health and had a positive effect on their oral health behaviour (98). Simple interventions can have significant benefits and any kind of intervention that increases awareness of the importance of oral health could be beneficial.

### 4.5.1 Limitations

The majority of work was carried out by one reviewer (HJ); to counteract any bias, a protocol was constructed and adhered to and a small number of studies for which there were concerns about inclusion were discussed in supervision for a second opinion. Data were extracted and entered into a database and double checked for accuracy before being used in the analysis.

### 4.5.2 Future directions

The COMET initiative is trying to establish 'Core Outcome Measures in Effectiveness Trials' to create data sets that are the minimum that should be measured and reported in all effectiveness trials of a specific condition (167). The data sets that are being designed are suitable for use in randomised controlled trials as well as other research. Core outcomes would make it easier for the results of trials to be compared, contrasted and combined in research, like a meta-analysis in a systematic review. This will help overcome similar problems to those which have been encountered in this systematic view: four relevant studies have been identified but they cannot be combined due to the different outcome measures used.

### 4.5.3 Conclusion

There is very little evidence for the current guidance for oral health interventions for people with serious mental illness from good quality, large, randomised controlled trials. Two of the trials included in this review also received sponsorship and in one of the trials this involved supplying participants with electronic or manual toothbrushes. This would not be sustainable in the United Kingdom within the National Health Service. Evidence indicates that the oral health of people with serious mental illness is poor compared to the general population. Guidelines suggest that the oral health of people with serious mental

illness should be monitored, and that they should receive advice and education on the importance of oral health as part of standard care.

There are currently only four randomised controlled trials that have been identified which have compared an oral health intervention with standard care for people with serious mental illness. The findings indicate that improving knowledge regarding oral health and hygiene practices may be beneficial, and that motivational interviewing also significantly improved oral health knowledge. A tooth brushing reminder system was found to reduce plaque to a greater extent than people who just used a mechanical toothbrush, so being prompted about oral hygiene may be beneficial. Oral health education and oral hygiene training were both found to significantly reduce plaque and an education session was found to reduce plaque more than an oral hygiene brochure. A mechanical toothbrush made participants teeth feel cleaner and look whiter than an ordinary manual toothbrush. But most found the mechanical toothbrush was not easier to use as it was big and heavy. None of the trials monitored basic oral health outcomes. A simple but effective intervention involving an element of education or advice that encouraged and monitored good oral hygiene behaviour that would also be sustainable within the NHS could really make a difference.

The next chapter describes the design and implementation of a cluster randomised controlled trial of an oral health intervention for people with serious mental illness. The guidelines from the British Society for Disability and Oral Health (2) were adapted to be used as an oral health intervention within the context of a cluster randomised controlled trial within the East Midlands early intervention in psychosis service.

## CHAPTER FIVE. An oral health intervention for people with serious mental illness: a cluster randomised controlled trial

### 5.1 Introduction

The systematic review of the prevalence of oral health and hygiene habits, dental treatment needs and professional dental treatment (Chapter Two) has supported previous research concluding that people with serious mental illness have poor oral health compared to the general population. As it has been established that the oral health of people with serious mental illness is poor, efforts should be made to attempt to improve it. Possible reasons why people with serious mental illness have poor oral health have been identified including mental health professionals may shy away from providing physical health care due to a perceived lack of training and self-confidence (Chapter Three). Service users often experience barriers to dental treatment and dentists also report a lack of training, and that they would appreciate mental health professionals supporting service users at appointments.

A Cochrane systematic review of oral heath advice interventions for people with serious mental illness found no relevant randomised controlled trials that fit the inclusion criteria (3). There are a small number of existing randomised controlled trials that have designed and tested an intervention with the aim of improving the oral health of people with serious mental illness, but none of these trials have measured basic oral health outcomes (Chapter Four).

Integrating preventative dental programs into standard care for people with serious mental illness has been recommended by recent studies (57, 104, 168), with the suggestion that mental health professionals should assist their patients with looking after their oral health (25). This was also a conclusion drawn from the review in Chapter Three. The main focus should be on regular tooth brushing and providing education and advice to those with serious mental illness with regard to their daily oral hygiene behaviour (59). The British Society for Disability and Oral Health guidelines published in 2000 made a number of

recommendations for the oral health care for people with serious mental illness, including providing oral health advice, support, promotion and education addressing individuals' oral health needs (2).

The previous chapters suggest that areas to be improved upon are good oral hygiene behaviour for service users (regular tooth brushing), attending regular dental appointments for a check-up, improved training for mental health professionals, incorporating oral health into standard care for people with serious mental illness, and mental health professionals supporting service users at dental appointments. In this chapter, the methodology, findings, and lessons learned from a pragmatic cluster randomised controlled trial of a simple oral health intervention for individuals with serious mental illness will be discussed.

### 5.2 Objectives

To examine whether dental awareness training for Care Co-ordinators plus a dental checklist leads to a clinically significant difference in the oral health behaviour of people with serious mental illness.

### 5.3 Ethical considerations and research governance

This study was approved by the Nottingham Research Ethics Committee (REC) (REC reference 11/EM/0205) as well as Nottinghamshire Healthcare NHS Trust, Derbyshire Healthcare NHS Foundation Trust and Lincolnshire Partnership NHS Foundation Trust, prior to commencement. The trial was registered at www.isrctn.com (Current Controlled Trials ISRCTN63382258). All data were made anonymous and stored securely. Individuals were not paid to participate in the trial although funds had been set aside to refund any costs for travel associated with the trial that was beyond receiving standard care, but this did not occur. Each Early Intervention in Psychosis team involved was provided with £1000 to cover any additional administrative cost incurred as a result of taking part in the trial.

### 5.4 Design

It has been reported that it can take 17 years for research evidence to change clinical practice (169, 170). This trial was designed so that it fit within standard care as much as possible. This was done so that it caused minimal disruption, but also so that the findings might have been clinically relevant which if the intervention was found to be effective this would hopefully reduce the amount of time that it would take to integrate the intervention into standard care. Care Co-ordinators were trained to deliver the intervention, rather than it being delivered by a researcher as this reflects what would happen in the real world setting. As can be seen from the previous chapters, very few trials have been undertaken in this area. This is a pioneering trial that aims tol set a standard and will allow researchers in the future to have some benchmark off which to work.

#### 5.4.1 Setting

The trial was conducted as part of standard care provided by the National Health Service (NHS) Early Intervention in Psychosis (EIP) teams in Nottinghamshire, Derbyshire and Lincolnshire (UK). These East Midlands counties have a mixture of urban and rural areas with a diverse population. The EIP teams provide intensive treatment and support to people with a first experience of symptoms such as hearing voices or those who develop unusual beliefs which may indicate the onset of psychosis. Care Co-ordinators are the main contact people for service users throughout their involvement with the service and it is therefore the Care Co-ordinators who delivered the intervention in this trial to their service users. The multisite design will allow the findings to be more generalizable to the wider population (external validity) than the findings of a single-site trial due to the more varied sociodemographic characteristics of participants (171, 172).

#### 5.4.2 Sample size

It is difficult to determine the number of people that need to be recruited to generate clinically significant data regarding the effect of an oral health advice intervention on the oral health of people with a serious mental illness as no previous trials of this sort exist (3). The study was designed in consultation with

clinicians and service users in design workshops; one of the aims of these workshops was to gain an impression of the size of difference that would lead to a change in clinical practice. These estimates were not formally recorded, but consensus suggested a range of between 10% to 20% and an estimate of the sample size for the mid-way point was created (Table 11).

Complicating the sample size calculation further was the study design; there were 10 EIP teams across the three NHS Trusts and Care Co-ordinators within each of those teams who each brought individual differences to the trial as each Care Co-ordinator would have a different level of professional experience.

It was decided that cluster randomisation should be used, the justification for this was to minimise a risk of 'contamination'; the intervention was simply a list of questions so it would be hard to ask and have any control over whether a Care Co-ordinator discussed oral health with one service user and not another (173). It was also thought that it would make being involved in the trial easier for the EIP teams if everyone in the same team was delivering the same intervention at the same time. The EIP teams were randomised as a whole team rather than at the individual patient level.

Intraclass correlation co-efficient (ICC) in cluster trials are difficult to estimate if no previous studies exist and not to take clustering into account would lead to ignoring the potential for a unit-of-analysis error (174-176). Simply estimating that we could randomise the people for whom the 10 teams provide care into two groups was not deemed to be an accurate reflection of the power of the study. This has to be multiplied by a design effect to adjust for the clustering. There were two levels of clustering within the trial, the EIP teams are the clusters that were randomly allocated to receive the interventions but there are also clusters within the teams; the individual Care Co-ordinators. Non-cluster N was calculated using the Stata 11 with alpha = 0.05, power = 0.80. The design effect (DE) was calculated considering service users were clustered within each individual Care Co-ordinator and overall EIP team and on the assumption that

each Care Co-ordinator saw on average 10 service users (DE = 1+(10-1)*0.1 = 1.9), with an intra-cluster coefficient of 0.1 as a best guess. Assuming that 5% of the service users who receive standard care visit a dentist, to detect a 15% increase in the proportion of those who visit a dentist in the dental intervention arm with 80% power at 0.05 significance level, we needed 176 service users for a single centre trial, and after adjusting for the cluster effect by multiplying this by the design effect, we needed to recruit 334 service users. After further adjusting for 20% of service users lost to follow up, the final number of service users we needed to recruit was calculated as 418. Other situations with various proportions of visits to a dentist in standard care are also presented in Table 11.

Table 11. Sample size needed to detect an absolute difference of 15% (α = 5%, power = 80%).

| Standard care, % | Monitoring, % | Non-cluster N (total) | Multiplied by design effect | Adjusted for 20% dropout |
|---|---|---|---|---|
| **5** | 20 | 176 | 334 | 418 |
| **10** | 25 | 226 | 430 | 538 |
| **15** | 30 | 268 | 510 | 638 |
| **20** | 35 | 302 | 574 | 718 |
| **25** | 40 | 330 | 628 | 785 |
| **30** | 45 | 352 | 670 | 837 |

### 5.4.3 Randomisation

This trial was limited by the number and size of the EIP teams as well as by the willingness of the Care Co-ordinators to deliver the intervention. The Nottingham Clinical Trials Unit (CTU) created a computerised randomisation program that was used to allocate the EIP teams randomly to receive the dental intervention or standard care. The EIP teams were grouped into pairs according to location

and size of team, and were each assigned a letter of the alphabet to anonymise them. The teams were block randomised; the block being the number of teams within each county, this ensured that each county received some degree of exposure to the intervention. One team in the pair was allocated to the dental intervention and the other to standard care. Randomisation was stratified to ensure that both the dental intervention group and standard care group were roughly equal in terms of team location, number of Care Co-ordinators within the team and size of caseloads.

### 5.4.4 Inclusion and exclusion criteria

This trial was quite ambitious as all EIP teams in Nottinghamshire, Derbyshire and Lincolnshire were invited to participate. All service users under the care of a Care Co-ordinator in one of these teams aged 18 years or above were included. Any concomitant treatments were allowed. Any EIP team that did not wish to take part and any individual Care Co-ordinator who did not wish to take part were excluded. The data from service users under the age of 18 at randomisation were not collected. Teams or Care Co-ordinators within each team were able to withdraw consent at any time. All data up to the point of withdrawal were used. Withdrawal from the study would result in resumption of standard care.

### 5.4.5 Procedure

EIP team managers were asked to consent to the trial being conducted within their teams. Consent was sought from Care Co-ordinators and service users were asked by their Care Co-ordinator if they agreed to their Care Co-ordinator completing the dental checklist during their regular appointment. Service users did not give formal consent for this trial, agreeing to answer the questions on the dental checklists was their 'participant assent'; this is standard in cluster randomised trials (173). This was due to the intervention being aimed at the Care Co-ordinators who received the dental awareness training, and it was the effect of this training and the checklist which was measured by the trial and not the responses of each individual service user. It was thought that the effect of this combined intervention would influence the service users' awareness of their oral

health, even if they did not complete the checklist. It was made clear to the service users that they did not have to answer the questions if they didn't want to and that this would have no detrimental effect on their standard care.

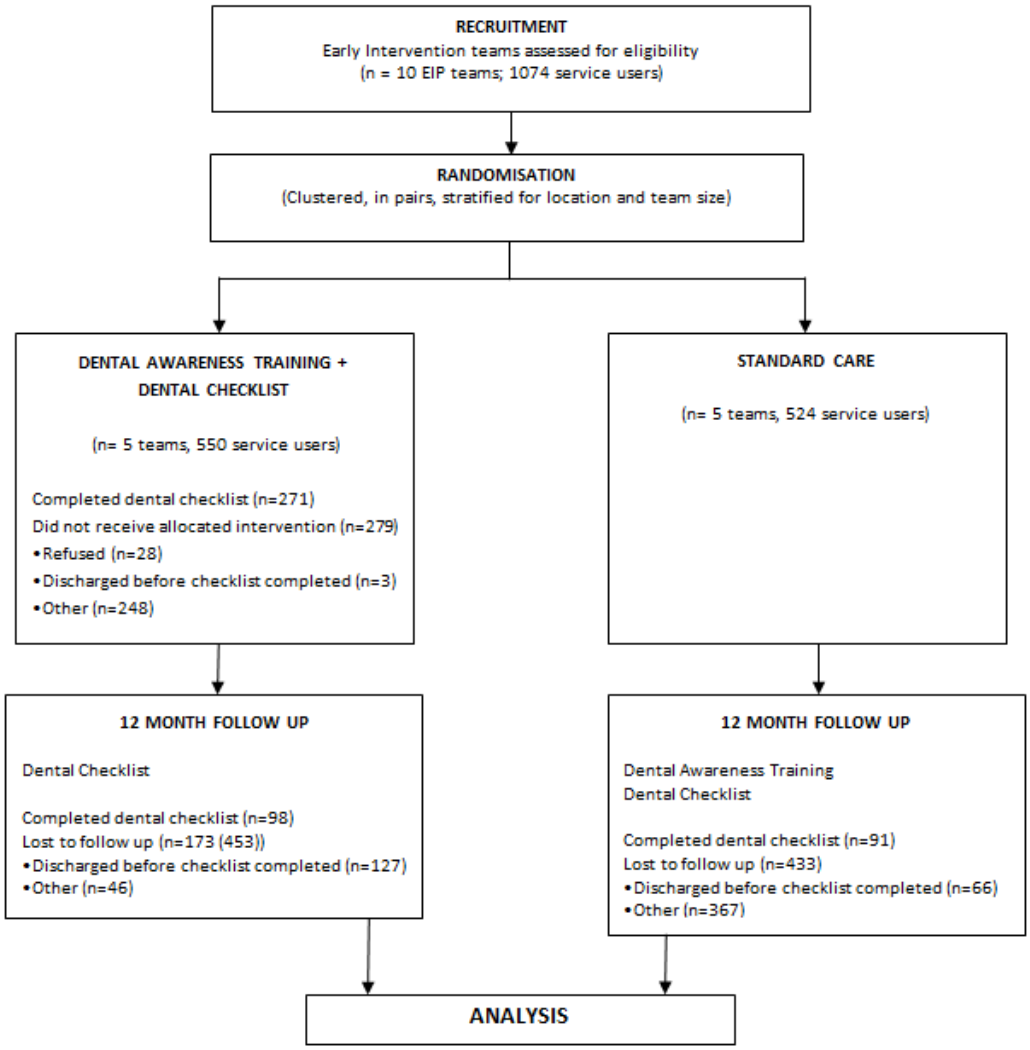


Figure 25. Flow of participants through the trial

### 5.4.6 Dental intervention

The trial was designed with considerable collaboration with EIP clinicians and service users to make it acceptable to be delivered with minimal disruption alongside standard care. The dental checklist (Figure 26 and Figure 27) was adapted from the British Society for Disability and Oral Health (BSDH) guidelines (2) in design workshops with researchers, clinicians, service users and carers. It covers questions regarding the service users current mental state to give an overall impression of the severity of their mental illness at the time of completing the checklist. There are questions about recent dental appointments, oral hygiene behaviour and current oral health state. Most questions are simple multiple choice, and for the short free text questions there are suggestions on the reverse of the sheet for main oral health difficulties and problems that oral health difficulties might cause to aid the Care Co-ordinators if required. The current mental state component of the checklist is from the CGI-Severity (CGI-S) which is a clinician-rated scale involving a single question rated on a seven point scale (177).

Demographic information about the EIP teams were collected including team location, number of Care Co-ordinators within the team, size of caseloads and distance to NHS dental services from the team base. The trial team did not have access to identifiable NHS data, only Clinical Studies Officers employed by each NHS organisation had access to any patient identifiable data. Each service user was allocated an anonymous trial ID number, the IDs were provided to the team and administration assistants or the Care Co-ordinators themselves assigned them to each service user. ID numbers consisted of a letter to identify the EIP team, then the Care Co-ordinator's initials then three unique numbers for service user – e.g. ABC123.

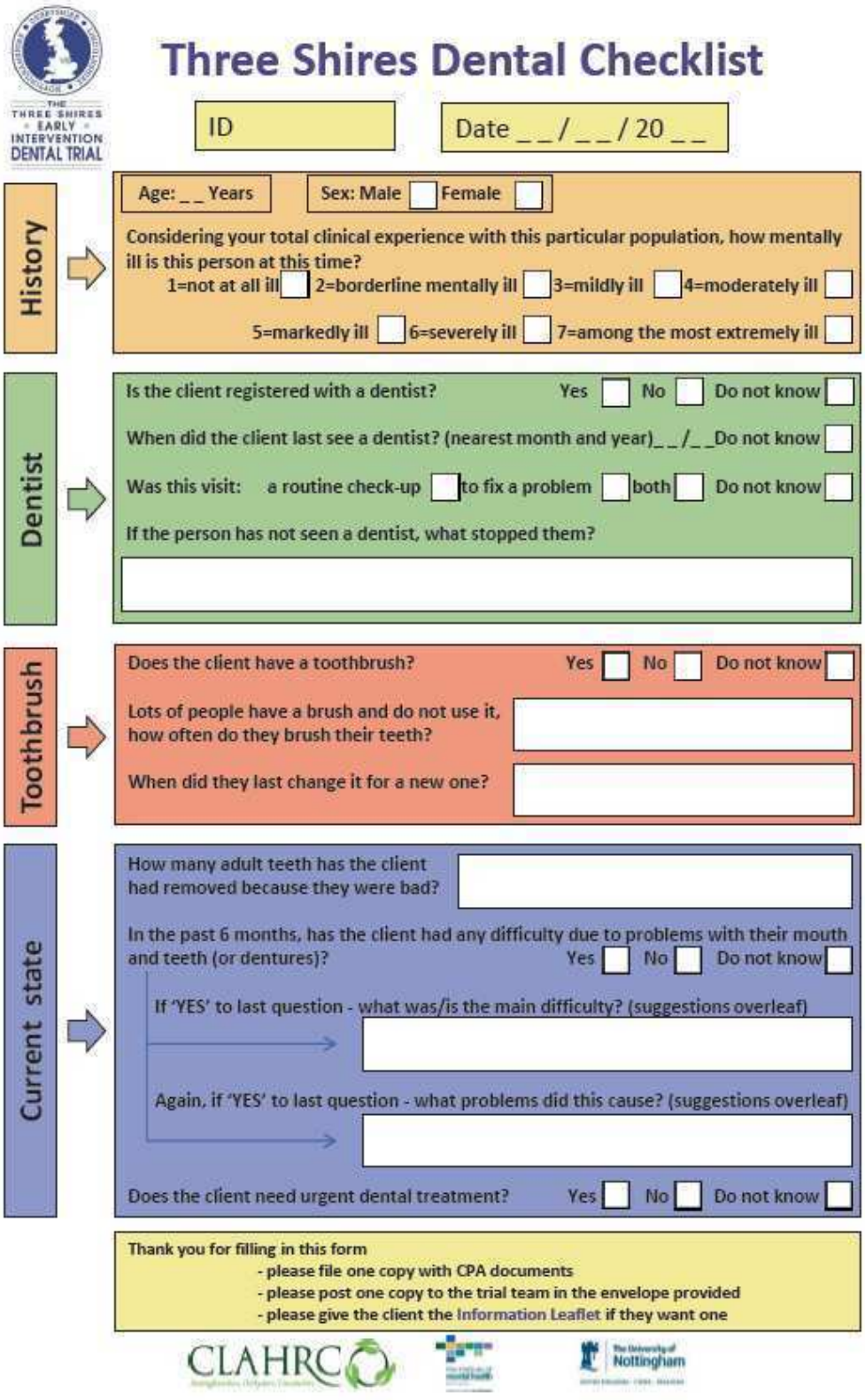


Figure 26. Dental Checklist (front)

**Suggestions for main difficulty**

bad breath
bleeding gums
clicking or grating noise in jaw
colour of teeth
deformity of mouth or face (e.g. cleft lip, cleft palate)
fractured tooth
improper filling or crown (e.g. broken, colour)
loose or ill-fitting denture
loose tooth
oral ulcer or spot
orthodontic appliance
position of teeth (e.g. crooked or projecting, gap)
receding gums
sensitive tooth
shape or size of teeth
swollen gums (gum abscess)
tartar
tooth decay (hole in tooth)
tooth loss
toothache

**Suggestions for problems that the oral health difficulty may cause**

eating food
speaking clearly
cleaning your teeth (dentures)
doing light physical activities, such as housework
going out, for example to shop or visit someone
sleeping
relaxing
smiling, laughing and showing teeth without embarrassment
with your emotional state, for example becoming more easily upset than usual
carrying out your major work
enjoying the contact of other people, such as relatives, friends or neighbours

Figure 27. Dental checklist (back)

After randomisation, EIP teams allocated to receive the dental intervention were approached to arrange a convenient time to hold a dental awareness training session at the start of the 12 month intervention period. This fitted within the usual multidisciplinary team meetings, but took around 30 minutes, including time for questions and discussion. Refreshments were provided by the trial team to help create a relaxed and informal environment where everyone felt able to ask questions. The training session covered the background and overall objectives of the trial, instruction on how to complete the dental checklist with service users, service user ID number allocation, how to return the completed checklists and a discussion about how to handle any adverse events. Information sheets about the study were provided to Care Co-ordinators and consent forms were signed if they were happy to participate. The EIP teams were provided with pre-paid envelopes to return the completed checklists to the trial team.

The checklists were printed on carbonless copy paper so that it would be quick and easy for one copy to be kept in the service users' clinical notes and the other returned to the trial team. The checklist was designed to take only a couple of minutes to complete; it is the brevity of the intervention that makes this trial accessible. Service users' mental health was closely monitored by their EIP teams as usual. The Care Co-ordinators were encouraged to complete the checklist with all of their service users at their earliest convenience. Care Co-ordinators were also encouraged to offer their service users an oral hygiene information sheet which contained basic oral hygiene tips and information on how to find an NHS dentist if they were not already registered with a dental practice (Figure 28). The Care Co-ordinators were asked to complete the history question on the checklist themselves, and then ask service users the rest of the questions about dental visits, toothbrush use and current dental state. If a service user did not want to take part, the Care Co-ordinator was asked to write their ID number on a checklist and send the blank form in prepaid envelopes provided back to the trial team. If a Care Co-ordinator thought that using the checklist may have a detrimental effect for the service user they were again asked to fill in an ID number on the dental checklist, write a note on the top of the checklist

confirming that the servicer user did not want to take part and post it back to the trial team in the pre-paid envelopes provided. If there were any adverse events, e.g. a service user passed away, Care Co-ordinators were asked to notify the trial team.

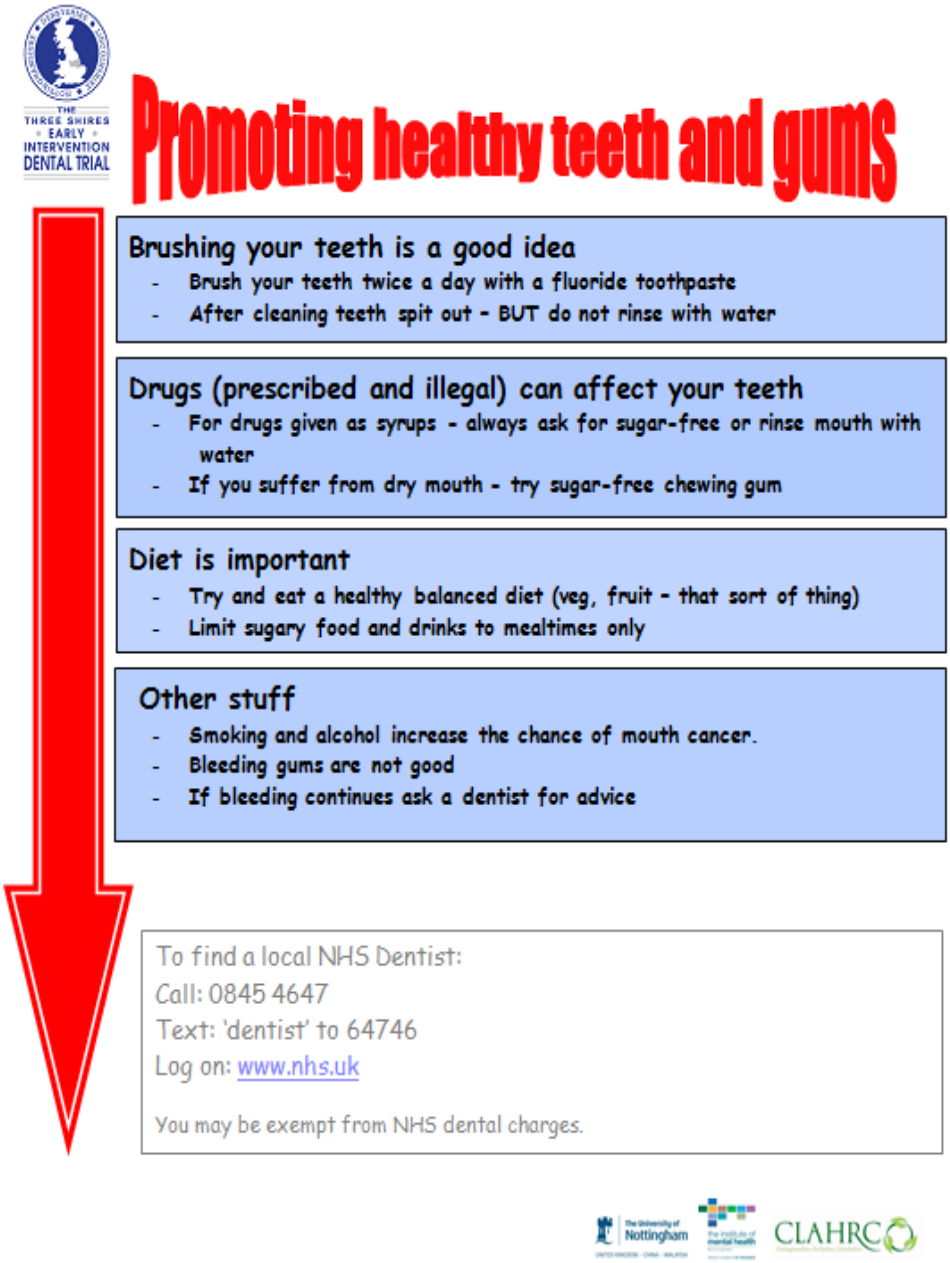


Figure 28. Oral hygiene information sheet

### 5.4.7 Standard care

EIP teams allocated to standard care continued to deliver standard care for 12 months. They received the dental awareness training and were asked to use the dental checklist 12 months after the intervention group, following the same procedure as the intervention group.

### 5.4.8 12 month follow up

Care Co-ordinators were prompted for the 12 month follow-up by the researcher attending the EIP multidisciplinary team meeting and providing a short refresher of how to complete the dental checklist. Dental checklists were completed for a second time for all service users. A total of 100 service users were also randomly selected from across all of the teams; their Care Co-ordinators were encouraged to ask them whether they would be willing to complete a quality of life measure with a researcher and provide permission for information about any recent dental appointments to be requested from their dentists (if they had visited a dentist within the previous 12 months). Although service users did not provide informed consent before completing the dental checklist with their Care Co-ordinator, informed consent was required for the quality of life measure (Oral Impacts on Daily Performance - OIDP) and dental appointments data outcomes.

The OIDP is a scale which assesses the impacts to which dental problems affect an individual's life on a daily basis (178) (Figure 29 and Figure 30). It is based on the World Health Organization's (WHO) International Classification of Impairments, Disabilities and Handicaps manual of classification relating to the consequences of disease (179) which was adapted for use in dental health (180). The OIDP consists of eight items that assess the impact of dental problems on basic activities and behaviours of everyday life. Questions concern whether or not problems with the mouth and teeth (or dentures) have caused the individual any difficulties with carrying out some everyday activities and behaviours. Acceptable psychometric properties have been found for the OIDP, as well as construct and criterion validity when applied to adult populations in Thailand, Greece and the UK (181, 182).

For the outcome concerning obtaining information about recent dental appointments, service users' dentists would be sent an information sheet about the study as a whole, a consent form and an oral health form (Figure 31) to complete for their patient. The oral health form consisted of questions that include the patients' last two dental appointment dates, treatment or recommendations that were given at the appointment, the Decayed Missing Filled Teeth (DMFT) (163) measure to gather a measure of the patient's clinical oral state which is a standardised oral health measure and one of the most common methods in oral epidemiology for assessing dental caries prevalence as well as dental treatment needs among populations. This index is based on clinical examination of individuals and simply counts the number of decayed, missing and filled teeth. The OIDP provides data on the impact of oral health on the service users' everyday quality of life, and the data from the dentists provides a clinical measure which can be used as a reliable indicator to the current state of the individuals' teeth and dental professionals' opinion.

THREE SHIRES EARLY INTERVENTION DENTAL TRIAL

**ORAL IMPACTS ON DAILY PERFORMANCE (OIDP): INTERVIEWER-ADMINISTERED QUESTIONNAIRE**

**ID**

This card shows some everyday activities / behaviours. I would like you to tell me whether or not problems with your mouth and teeth (or dentures) have caused you difficulty with each one of those in the past 6 months.

| | Q1 | | Q2 | | Q3 | Q4 | Q5 | Q6 |
|---|---|---|---|---|---|---|---|---|
| | YES | NO | Regular basis | Part of period | How often? | How much? | | |
| Eating food | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| Speaking clearly | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| Cleaning your teeth (dentures) | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| Doing light physical activities, such as housework | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| Going out, for example to shop or visit someone | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| Sleeping | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| Relaxing | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| Smiling, laughing and showing teeth without embarrassment | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| With your emotional state, for example becoming more easily upset than usual | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| Carrying out your major work | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |
| Enjoying the contact of other people, such as relatives, friends or neighbours | 1 | 2 | 1 → Q3 | 2 → Q4 | | | | |

**Q1.** In the past 6 months, have you had any difficulty ... ACTIVITY / BEHAVIOR... due to problems with your mouth and teeth (or dentures)?
**CODE "YES" OR "NO". FOR EACH ACTIVITY / BEHAVIOR CODED `YES', ASK Q2-Q6.**

**Q2.** Have you had this difficulty ... ACTIVITY / BEHAVIOR... on a regular basis over the past 6 months or only for part of this period?

| | |
|---|---|
| on a regular basis | 1 **ASK Q3** |
| only for part of this period | 2 **GO TO Q4** |

**CODE ONE ONLY, THEN ASK Q3 OR Q4 AS INDICATED.**

**IF RESTRICTED "ON A REGULAR BASIS" (CODE 1 AT Q2)**
**Q3.** During the past 6 months, how often have you had this difficulty .ACTIVITY / BEHAVIOR...?

| | |
|---|---|
| every day or nearly every day | 5 |
| about 3-4 times a week | 4 |
| about 1-2 times a week | 3 |
| about 1-2 times a month | 2 |
| or less often than once a month | 1 |
| (Can't say) | 9 |

**ENTER ANSWER CODE IN BOX UNDER Q3 ON GRID. GO TO Q5.**

Figure 29. Oral Impacts on Daily Performance (front)

THE THREE SHIRES EARLY INTERVENTION DENTAL TRIAL

**ORAL IMPACTS ON DAILY PERFORMANCE (OIDP): INTERVIEWER-ADMINISTERED QUESTIONNAIRE**

**ID**

**IF RESTRICTED "ONLY FOR PART OF THIS PERIOD" (CODE 2 AT Q2).**

**Q4.** For how much of the past 6 months have you had this difficulty...ACTIVITY / BEHAVIOUR..?

| | |
|---|---|
| for more than 3 months | 5 |
| for more than 2, up to 3 months | 4 |
| for more than 1, up to 2 months | 3 |
| for more than 5 days, up to a month | 2 |
| or for 5 days or less? | 1 |
| (can't say) | 9 |

**Q5.** And using a scale from 0 to 5, where 0 is no effect and 5 a very severe effect, how much effect would you say that this difficulty ...ACTIVITY / BEHAVIOR...has had on your everyday life?

| | |
|---|---|
| no effect | 5 |
| a very minor effect | 4 |
| a fairly minor effect | 3 |
| a moderate effect | 2 |
| a fairly severe effect | 1 |
| (can't say) | 9 |

**Q6.** Now, I am going to investigate the specific condition that caused this difficulty. Which one of the following oral conditions has caused this difficulty ...ACTIVITY / BEHAVIOUR...?

| | | | |
|---|---|---|---|
| toothache | 1 | Receding gums | 12 |
| sensitive tooth | 2 | tartar | 13 |
| tooth decay (hole in tooth) | 3 | oral ulcer or spot | 14 |
| fractured tooth | 4 | bad breath | 15 |
| tooth loss | 5 | deformity of mouth or face (e.g. cleft lip, cleft palate) | 16 |
| loose tooth | 6 | clicking or grating noise in jaw | 17 |
| colour of teeth | 7 | improper filling or crown (e.g. broken, colour) | 18 |
| position of teeth (e.g. crooked or projecting, gap) | 8 | loose or ill-fitting denture | 19 |
| shape or size of teeth | 9 | orthodontic appliance | 20 |
| bleeding gums | 10 | or any other reason? (please specify) | 88 |
| swollen gums (gum abscess) | 11 | (Can't say) | 99 |

Figure 30. Oral Impacts on Daily Performance (back)

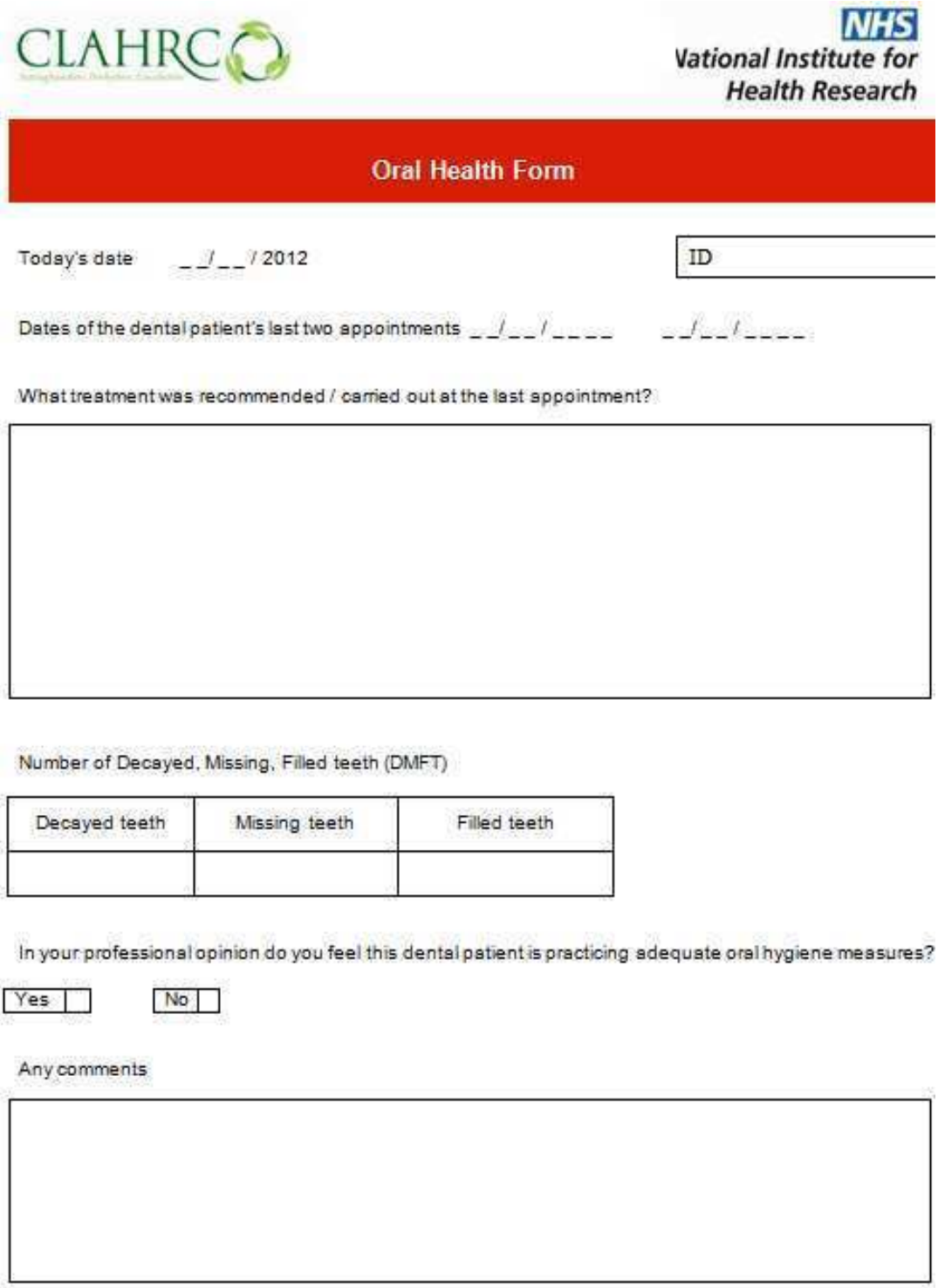


Figure 31. Oral health form

### 5.4.9 Outcomes

#### 5.4.9.1 Primary outcome

Number of service users who have visited a dentist within 12 months of exposure to the checklist as reported on the checklist.

#### 5.4.9.2 Secondary outcomes

Registered with a dentist, dental appointment within the last 12 months, owning a toothbrush, cleaning teeth twice a day, replacing existing toothbrush within the last six months, problems with mouth and teeth, OIDP, DMFT, professional dental treatment received.

## 5.5 Data analysis

### 5.5.1 Quantitative data

Exploratory analyses were undertaken and descriptive statistics were presented for background demographic variables and outcome by treatment groups (Table 12, Table 13, Table 14). Data were available for 393 participants. At baseline 271/550 service users completed dental checklists were returned. There were 28 service users who refused to complete the checklist, although reasons for refusal were not given, and three were discharged before their Care Co-ordinator could complete a checklist with them. Why a checklist was not completed by the remaining 248 service users who were allocated to receive the dental intervention is not known. Only 98/271 (36.1%) of service users returned a completed dental checklist at the 12 month follow up from the dental intervention. Of the 173 participants who were lost to follow up there were 127 who had been discharged before a 12 month follow up checklist could be completed and 46 were lost for reasons unknown. For those allocated to standard care 91/524 (17%) returned a completed dental checklist at the 12 month follow up. There were 433 service users who were lost to follow up, of which 66 were discharged before a checklist could be completed and 367 were lost for reasons unknown.

Ages were similar for both interventions with a mean age of 28.3 years in the dental intervention at 12 months follow up and 26.1 years in standard care. Both of the interventions were also relatively balanced for gender with the dental intervention having 69.2% male and standard care 62.6% male participants at the 12 month follow up. The severity of illness was concentrated at the milder end of the scale with only two participants rated to be among the most extremely ill in the dental intervention at baseline, no participant was given this rating at the 12 month follow up.

As cluster randomisation was used with categorical outcome variables, it was planned to use multilevel multinomial logistics regression analysis to check the unordered categorical outcomes variability at team level and examine the treatment effect (183). Missing values were explored by intervention and multilevel logistic regression with team as level 2 units were applied to examine the association between missing data and treatment status. Missing values were imputed using REALCOME software (184, 185). Analyses were conducted on an intention-to-treat basis (186). MLwiN was used to perform all multilevel modelling and STATA 11 was used to carry out exploratory analysis (187). Due to the vast amount of missing data that would need to be imputed, the original analysis was only run for the primary outcome. This decision was taken as the large amount of missing data raised questions about the reliability of the results. A study that questioned clinicians, researchers, service users, and carers about acceptable attrition levels in studies and found that 70-75% was generally found to be credible (188). Although this study referred to drug trials, at some point results become unreliable when there are large amounts of missing data. At the 12 month follow up 44.3% of participants in the dental intervention group and 58.2% of participants in the standard care group had visited a dentist within the last 12 months. This difference was not statistically significant (0.97 (0.47, 2.04), p=0.943) (Table 15).

One of the participants in the dental intervention group reported at baseline that they did not own a toothbrush; they had not seen a dentist in over 10 years as

they had had all of their teeth removed so had no need for a toothbrush. Three participants were also not sure whether they owned a toothbrush. At the 12 month follow up, the majority of those in the dental intervention group brushed their teeth twice a day (44.3%) but the majority of participants in the standard care group only brushed their teeth once a day (37.6%) with 34.2% brushing their teeth twice a day. The vast majority of individuals in both interventions had replaced their toothbrush within the last six months at the 12 month follow up with 82.1% in the dental intervention group and 84.9% in the standard care group. The number of teeth that had been extracted was very low; dental intervention mean 1.71 (4.48 SD) and standard care mean 1.48 (3.98 SD) (Table 15). The majority of participants had not experienced any problems with their mouth or teeth in the last six months, but 35.1% of those in the dental intervention group and 40% of those who received standard care had experienced a problem. Very few participants required urgent dental treatment with only 16% of participants who had received the dental intervention and 9.8% of those who had received standard care in need of treatment.

Table 12. Demographic data of participants who completed a dental checklist

| | Baseline Dental Intervention | | | 12 months Dental Intervention | | | 12 months Standard Care | | |
|---|---|---|---|---|---|---|---|---|---|
| | **n** | **(%)** | | **n** | **(%)** | | **n** | **(%)** | |
| **Sex** | **271** | | | **98** | | | **91** | | |
| Male | 186 | (68.6) | | 68 | (69.4) | | 57 | (62.6) | |
| Female | 73 | (27) | | 27 | (27.5) | | 28 | (30.8) | |
| Not disclosed | 12 | (4.4) | | 3 | (3.1) | | 6 | (6.6) | |
| | **n** | **Mean** | **SD** | **n** | **Mean** | **SD** | **n** | **Mean** | **SD** |
| **Age** (yrs) | **248** | 25.8 | 5.4 | **88** | 28.3 | 21.3 | **77** | 26.1 | 5.7 |
| | **n** | **%** | | **n** | **%** | | **n** | **%** | |
| **Severity of illness** | **243** | | | **86** | | | **82** | | |
| Not at all ill | 50 | (16.8) | | 16 | (18.6) | | 11 | (13.4) | |
| Borderline mentally ill | 57 | (19.1) | | 23 | (26.7) | | 14 | (17.2) | |
| Mildly ill | 58 | (19.5) | | 22 | (25.6) | | 19 | (23.2) | |
| Moderately ill | 44 | (14.8) | | 19 | (22.1) | | 29 | (35.3) | |
| Markedly ill | 24 | (8.1) | | 3 | (3.5) | | 7 | (8.5) | |
| Severely ill | 8 | (2.7) | | 3 | (3.5) | | 2 | (2.4) | |
| Among the most extremely ill | 2 | (0.7) | | 0 | (0) | | 0 | (0) | |

Table 13. Outcomes by treatment group

| | Baseline Dental Intervention | | 12 months Dental Intervention | | 12 months Standard Care | |
|---|---|---|---|---|---|---|
| | **n** | **(%)** | **n** | **(%)** | **n** | **(%)** |
| **Registered with a dentist** | **263** | | **96** | | **91** | |
| Yes | 186 | (70.7) | 65 | (67.7) | 60 | (65.9) |
| No | 65 | (24.7) | 25 | (26) | 26 | (28.6) |
| Do not know | 12 | (4.6) | 6 | (6.3) | 5 | (5.5) |
| **Visited dentist within last 12 months*** | **258** | | **97** | | **91** | |
| Yes | 166 | (64.3) | 43 | (44.3) | 53 | (58.2) |
| No | 56 | (21.7) | 25 | (25.8) | 28 | (30.8) |
| Do not know | 36 | (14) | 29 | (29.9) | 10 | (11) |
| **Reason for dentist visit** | **248** | | **91** | | **89** | |
| Routine check-up | 148 | (59.7) | 48 | (52.7) | 47 | (52.8) |
| Fix a problem | 69 | (27.8) | 31 | (34.1) | 30 | (33.7) |
| both | 24 | (9.7) | 8 | (8.8) | 7 | (7.9) |
| Do not know | 7 | (2.8) | 4 | (4.4) | 5 | (5.6) |
| **Own a toothbrush** | **264** | | **97** | | **89** | |
| Yes | 260 | (98.5) | 97 | (100) | 89 | (100) |
| No | 1 | (0.4) | 0 | (0) | 0 | (0) |
| Do not know | 3 | (1.1) | 0 | (0) | 0 | (0) |
| **Frequency of tooth brushing** | **256** | | **97** | | **85** | |
| Once a day | 89 | (34.8) | 38 | (39.2) | 32 | (37.6) |
| Twice a day | 113 | (44.1) | 43 | (44.3) | 29 | (34.2) |
| Other | 54 | (21.1) | 16 | (16.5) | 24 | (28.2) |
| **Replaced toothbrush within the last six months** | **253** | | **95** | | **86** | |
| Yes | 212 | (83.8) | 78 | (82.1) | 73 | (84.9) |
| No | 18 | (7.1) | 9 | (9.5) | 8 | (9.3) |
| Do not know | 23 | (9.1) | 8 | (8.4) | 5 | (5.8) |
| **Problems with mouth and teeth in last six months** | **245** | | **94** | | **90** | |
| Yes | 80 | (32.7) | 33 | (35.1) | 36 | (40) |
| No | 162 | (66.1) | 57 | (60.7) | 53 | (58.9) |
| Do not Know | 3 | (1.2) | 4 | (4.2) | 1 | (1.1) |
| **Require urgent dental treatment** | **245** | | **94** | | **82** | |
| Yes | 14 | (5.7) | 15 | (16) | 8 | (9.8) |
| No | 226 | (92.2) | 78 | (83) | 67 | (81.7) |
| Do not know | 5 | (2) | 1 | (1) | 7 | (8.5) |

*Primary outcome

Table 14. Teeth extracted

| Baseline Dental Intervention | | | | 12 months Dental Intervention | | | | 12 months Standard Care | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **n** | **Range** | **Mean** | **SD** | **n** | **Range** | **Mean** | **SD** | **n** | **Range** | **Mean** | **SD** |
| 252 | 0-32 | 1.06 | 3.13 | 90 | 0-28 | 1.71 | 4.48 | 89 | 0-32 | 1.48 | 3.98 |

Table 15. Estimates of treatment effects on outcomes

| Outcomes | Treatment Effect (95%CI) |
|---|---|
| **Visited a dentist within the last 12 months** | 0.97 (0.47, 2.04), p=0.943 |

### 5.5.2 Qualitative data analysis

#### 5.5.2.1 Reasons for not having had a dental appointment within the last 12 months

Thematic analysis was used to identify common themes within the answers provided for why the service users had not had a dental appointment within the last 12 months, as proposed by Braun & Clarke (2006) (189). The data are from the service users' perspective but told to the Care Co-ordinator, who then wrote responses on the dental checklist. Data were entered into a separate database and were re-read to re-familiarise the depth and breadth of the data to search for meanings and patterns. A data-driven approach was used. Initial lists of ideas were created by highlighting key features of the data set and then grouping them together. The groups were then reviewed and developed into themes of common data presented below.

**Anxiety**

Dental anxiety is common but is heightened for people with serious mental illness with around 49% of the general population feel nervous about going to the dentist (190). One participant's explanation for why they hadn't seen a dentist in recent years was because they were *"anxious with the idea of someone looking or poking in his mouth"*. Other participants reported that they *"felt uncomfortable"* seeing a dentist. Dental anxiety is also associated with poor oral

health with greater anxiety linked to having more decayed teeth and fewer filled teeth (191). Many often fear that if they haven't had a dental appointment for a long time the fear of attending increases as they worry about the reception they will receive after so long (192). For some visiting a dentist was not possible because they *"…struggle getting out due to social anxiety."* Social anxiety is a common co-morbidity in people with serious mental illness (193), those who have social anxiety experience considerable difficulty in carrying out everyday life activities (194), as such dental appointments may be avoided. Individuals with dental anxiety can sometimes be caught in a cycle where the fear of what might happen if they do visit a dentist, pain, and guilt from having avoided dental appointments in the past, actually prevent good oral hygiene behaviour and appropriate treatment (195).

**Previous experience at the dentist**

A previous bad experience at the dentist is known to increase anxiety (196). Having the belief that dental treatment will be painful increases the likelihood of avoiding dental appointments (197). One participant's reason for not having seen a dentist in the last 12 months was because at their last dental appointment where they received treatment they reported that the *"dentist did not give anaesthetic."* Another service user said that they have previously received *"poor treatment from their dentist"* in that they *"believe they treated the wrong tooth".*

**No need to visit a dentist**

Regular dental check-ups are encouraged, but not everyone attends appointments as regularly as advised by their dentist. A theme of the idea of not needing to see a dentist occurred in participant responses. Many participants suggested that they only thought about seeing a dentist when they experienced some kind of dental problem; *"…only goes to dentist when there's a problem", "client does not think he has a problem e.g. no pain"* and there was "*no need as no problems".* This indicates that dentists are seen as more of an emergency service rather than there to check on an individual's general oral health. This is in

keeping with previous research that people with a mental illness tend to attend dental appointments only when they are in pain (25, 30, 113, 122).

The idea of regular dental appointments as being important seemed to stem from individual's family way of life; when asked why they hadn't seen a dentist one participant responded with *"never had problems with my teeth, can't remember ever going."* Some participants suggested that it *"hadn't crossed their mind",* that they *"don't think about it",* and that there was a sense of visiting a dentist was *"not a priority within the family."* They were *"not used to going to the dentist"* or had *"never been to a dentist*". Although oral health has been shown to be important to self-esteem as it is linked to personal appearance, this was not seen as important to everyone because a reason for not seeing a dentist regularly was given as *"laziness, I didn't care about my personal appearance."*

**Financial reasons**

Some of the participants indicated that they only visited a dentist when they experienced a dental problem rather than attending regular dental check-up because of financial reasons. The *"cost of dental work"* was reported as a reason why some participants had not had a dental appointment for many years. Financial reasons for not having had a dental appointment within the last 12 months were mainly due to participants themselves not being able to afford the cost of treatment, but the cost to the dental service also seemed to be an issue. Missing appointments costs the NHS a lot of money, and it has already been highlighted in Chapter Three that individuals with a mental illness may be likely to miss appointments due to issues surrounding their mental illness. One participant reported that they *"cannot obtain registration due to being taken off the list for missed appointments."* The Care Co-ordinator for this individual also indicated that they thought they required urgent dental treatment, although further details were not provided. Support from the Care Co-ordinator may help the service user to find an NHS dentist, make an appointment and then attend with the support of their Care Co-ordinator.

**Service reasons**

Long waiting lists for a dental appointment was also provided as a reason for not having seen a dentist; *"waiting list delay, it put me off."* Dental practices also have a limit on the number of patients they can accept, some participants' responses included being unable to find a dentist if they had moved area or if their previous dentist had closed; *"don't know where one is", "due to moving around over the past five years."*

#### 5.5.2.2 Difficulty due to problem with the mouth or teeth

The vast majority of data provided for this outcome were one or two word answers so content analysis was thought to be the most appropriate method of analysis. Content analysis is used to observe the presence of certain words which can then be quantified. Responses were very similar for participants in both the dental intervention group and standard care group. Pain was mentioned by 18 participants, mainly in reference to having toothache currently. Problems with gums, like bleeding, were reported by 12 participants and a further four participants had a mouth ulcer or an abscess. A problem with a filling in a tooth was said to be a problem for 12 participants, some of the participants had previously been told that they required a filling but were too anxious to have the treatment and so avoided the procedure despite also being in pain, and others reported that a filling had fallen out and needed replacing but they either did not want treatment due to anxiety or "*haven't got round to making an appointment yet".* A very similar picture was present for those who currently had a loose tooth or a broken tooth. Sensitive teeth were a problem for eight participants, and seven were experiencing problems with their wisdom teeth. The average age of the participants is around the time that wisdom teeth can cause problems so it is not surprising that this has been reported. Halitosis was causing concern for two of the participants and a further two participants had problems with their braces.

#### 5.5.2.3 Impact of the dental difficulty

Responses were similar for participants in both the dental intervention group and standard care group. Problems with the mouth or teeth can cause significant

problems for individuals. The main problem that the dental difficulties caused the participants was simply cited as *"pain"* by 11 participants. Whilst two of the participants reported that the dental difficulties did not cause them any particular problems, two participants felt embarrassed or ashamed because of the difficulties with their mouth or teeth and three felt that it affected their social interactions, *"I didn't go out to see people, felt ashamed"* and another participant reported that it stopped them from *"eating food, cleaning teeth, going out, smiling and enjoying contact with others"*. Having teeth extracted makes eating more difficult and can have a significant impact on diet (198). The mouth is also an important part of overall appearance (199). Self-perceived oral health has been shown to affect psychological well-being (200). Three participants found that the problem with their mouth or teeth prevented them from brushing their teeth or caused problems with oral hygiene, *"bleeding when brushing"* and *"neglect of oral hygiene"*. A further two participants had trouble sleeping because of the dental difficulties they were experiencing. One participant also noted that they were *"worried that it may be due to the medication."*

### 5.5.3 Oral Impacts on Daily Performance and data from dentists

Only one participant gave consent to participate in this part of the study, so it did not feel appropriate to reproduce the data.

### 5.5.4 Adverse events

No adverse events were reported to the trial team.

### 5.5.5 Participant evaluation

An evaluation with twenty staff and service users who had participated in the trial had initially been planned. No participants were willing to complete an evaluation. The evaluation intended to cover questions concerning their impression of the dental checklist including any particular likes, dislikes or improvements to be made, any suggestions about what would help Care Co-ordinators to use the checklist or anything that prevented or made it difficult to

use the checklist, and whether the dental checklist had had any impact on the clinical practice for Care Co-ordinators.

The interaction between participants and study design can influence missing data (201). It is thought that repeated requests to complete the dental checklists may have put additional pressure on the clinical teams and as such they did not want to spend any additional time on any aspect of the trial. The fact that no evaluations were completed highlights the extent to which the Care Co-ordinators did not engage with the study. Care Co-ordinators were relied upon to invite the service users and if the Care Co-ordinators themselves did not wish to take part, it is not surprising that there were also no service user evaluations.

**5.6 Conclusion**

This pragmatic cluster randomised controlled trial of an oral health intervention for people with serious mental illness randomised 1074 service users from EIP teams in the East Midlands of England to receive a dental intervention or standard care. At baseline only 271/550 service users randomised to the dental intervention group completed dental checklists. Only 98/271 (36.1%) of service users returned a completed dental checklist at the 12 month follow up and for those allocated to standard care 91/524 (17%) returned a completed dental checklist at the 12 month follow up. The reason why most of the participants were lost from the trial is unknown. Repeated requests were made to Care Co-ordinators to complete a checklist but this did not happen for all of the service users. Some participants were discharged from the service before a checklist could be completed, but for the others there is no indication of the reason. Data for 189 participants at the 12 months follow up were collected.

From the available data no significant differences were found; the checklist did not improve oral health behaviour in people with serious mental illness. At the 12 month follow up all participants in both the dental intervention group and standard care group owned a toothbrush. The majority of those in the dental intervention group brushed their teeth twice a day but the majority of

participants in the standard care group only brushed their teeth once a day. Most participants in both the dental intervention group and standard care group had replaced their toothbrush within the last six months. Very few participants had had teeth extracted and the number of teeth removed per participant was also low. The majority of participants had not experienced any problems with their mouth or teeth in the last six months. Of those who had experienced a problem with their mouth or teeth the main difficulties given were pain, problems with gums, problems with fillings, loose teeth or a broken teeth, sensitive teeth, wisdom teeth problems, halitosis, and problems with braces. The impact of these difficulties varied with some participants saying there was no impact and others reporting problems eating, sleeping, drinking, socialising and being embarrassed of their teeth as a result.

Suggestions for missing data have been classified into categories concerning study participants, study design, and interaction of the study participants (201). Participants might have been uncomfortable answering some of the questions on the dental checklists and so missed them out, or may have initially read through the questions and then refused to answer any of them. The design of this study meant that all participants cared for by the clinical team were randomised, if an individual did not wish to take part they counted towards the missing data and that is why the level of missing data in this trial is so large. Many participants who were randomised did not complete a dental checklist. This aspect of the design should be considered in future studies to minimise impact. It is not possible to come to a decision as to whether the missing data from this trial led to there being an unrepresentative sample as there are no details for those participants; it was not reported whether their current mental state was a contributing factor or whether another factor was responsible.

Consideration is required with regards to the design concerning service users being discharged from a service but having already being randomised in the trial. Due to the researcher not having identifiable information for trial participants it was not possible for individuals to be contacted and as the intervention was designed to fit in with standard care, the Care Co-ordinators were also unable to

complete checklists with anyone who had been discharged, and so no data were obtainable for them. There were also only a small number of clusters in the trial, teams were matched into pairs for size and location, previous research has indicated that "*for small studies, it is unlikely that effective matching would be possible*" and that "*matching may be overused as a design tool.*" (202) (p336–337). Matching was used in this trial so that the dental intervention and standard care groups would be roughly balanced, but this may not be necessary and due to the very small number of options the matching process may not have been accurate enough. If future studies contain a small number of clusters then matching should be avoided.

The design of the trial meant that a number of participants who were randomised did not receive their allocated intervention. Randomised controlled trials depend on people willing to take part in the study. If high levels of participation are not achieved there can be implications for statistical power, internal validity, and external validity (203). Difficulty in recruiting participants can also have practical and financial implications as recruitment may have to continue for longer than initially designated if a sample size has not been achieved. A systematic review of improving recruitment and retention in trials proposed three important areas of concern: the study infrastructure, involvement and engagement of professionals and patients, and methodological innovation (204).

The ID numbers for each service user involved a letter to identify the EIP team, the Care Co-ordinator and then three unique numbers. This level of detail caused some problems as a small number of service users changed Care Co-ordinator during the trial. The result was some dental checklists were returned with no ID number and so could not be used in the analysis. It would have been easier for everyone involved if just the three unique numbers were used as ID numbers. It would have been useful to have had information on any medication that service users may have been prescribed for their mental illness, especially as one participant was worried that the dental problem that they were experiencing

may have been due to the medication that they were being prescribed. This was a question on the original BSDH checklists but was omitted from the adapted checklist for this trial as concerns regarding how much time the checklists would take up and how important the significance of information would be were raised. This is linked to a possible reason why some checklists may not have been completed. Some of the Care Co-ordinators involved in the trial had attended the design workshops at the start of the study. During the dental awareness training sessions some commented that their suggestions had not been incorporated into the checklist. Unfortunately it is not always possible to implement everyone's suggestions, the checklist needed to fit into standard care easily so it was kept quite short so that it would not take long to complete. This led to some of the Care Co-ordinators possibly feeling as though they had not been listened to and they then may have been reluctant to participate.

A Cochrane systematic review of interventions that had been designed to improve recruitment to randomised controlled trials has suggested some strategies to increase recruitment including telephone reminders, having an open-trial design so that participants know what intervention they are receiving rather than being blind to intervention, opt-out strategies for participants, and also financial incentives (205). This review included 45 trials involving 46 different interventions, most of the interventions targeted the trial participants with only a few studies having interventions that were being directed at recruiters. The number of visits made to trial sites did not make a significant difference to recruitment rates in two studies (206, 207). The number of visits to trial sites was thought to be a possible reason why only a small number of completed dental checklists were returned for this trial. The initial idea of multiple visits to the EIP teams was to keep the study fresh in the Care Co-ordinators' minds in the hope that they would then complete their remaining checklists with their service users at their earliest convenience. There was a concern about whether the repeated visits had too much of an impact on the Care Co-ordinators' time and therefore decreased enthusiasm for their continued participation in the study. Other studies suggest that repeated visits

had no effect on recruitment which indicates that there is not a requirement for multiple visits to trial sites in future studies as it may not actually improve recruitment rates. Telephone reminders to follow-up written invitations to participate in research improved recruitment for two studies (208, 209). In future studies, telephoning rather than visiting trial sites may improve recruitment. It may be seen as less of an impact on time and therefore be better received which will then lead to the desired impact of improving recruitment.

The use of small incentives has been shown to increase recruitment in a study of smoking cessation when £5 was included with the study information sheet and consent form (210). Payment of different amounts has also been used for participation, albeit in two hypothetical trials, willingness to participate significantly increased with payment (211). Although the EIP teams were each provided with £1000 to offset any additional administrative costs associated with the trial, it is unlikely that Care Co-ordinators would have seen any of this even though it was they who completed the checklist with their service users during one of their standard appointments. During one of the dental awareness training sessions one Care Co-ordinator asked "*what's in this for me*". The researcher responded with the possible perceived benefits to the service users oral health, but this also highlighted how the Care Co-ordinators may begrudge research. An incentive directly for the Care Co-ordinators may have increased the amount of dental checklists that were completed but as the checklist was being delivered as part of standard care it may not be possible to provide any sort of reward.

Steps that could be taken to improve recruitment have been suggested as having a clinically important question that is being tested, minimising the workload of clinicians involved, and specifically not asking clinicians to be responsible for gaining consent from their patients to participate in the trial (212, 213). There is a randomised trial design that can overcome the problem of trial designs creating a barrier to recruitment. It has the advantage that participants know whether an experimental treatment is to be used before providing consent (214). In Zelen's design, participants can be randomised to intervention or control as

normal. The participants allocated to receive the control receive standard care and the participants that were allocated to receive the intervention can be approached and asked if they would be happy to receive the intervention being offered to them. If they do not wish to receive the intervention being offered they then receive standard care. Analysis is conducted with participants retaining their original randomised assignment. Increasing numbers of participants can overcome loss of statistical efficiency. This type of design could have been used in the dental trial to improve the numbers of participants recruited to the study.

### 5.6.1 Limitations

A limitation of this trial was low recruitment and a low follow up rate. The study did not recruit the number of participants that was stated by the sample size calculation. It is not possible to draw any real conclusions due to this as the data cannot be truly trusted due to the amount that was missing. It was also not possible to do all of the planned analyses because of the lack of data. The NHS has a tight budget and cuts are often made to services. At the start of the trial it was brought to light that some of the EIP teams were being amalgamated to save money. This was dealt with in the randomisation without issue and all service users would continue to receive care. The issue was the effect that this may have had on the mental health professionals as staffing levels were being reduced. As participant evaluations were not completed, it is not possible to understand fully why some Care Co-ordinators did not complete all of the dental checklists with their service users, but it is possible that additional pressures played a part. Care Co-ordinators may have had their workload increased which would have reduced the amount of time they would have been able to spend with each individual service user, in turn reducing the possibility of completing the dental checklist with their service user. It is also a possibility that the Care Co-ordinator may have been reluctant to participate in research if they felt that their job was at risk; they may have had no interest in research or have wanted to focus on patient care.

There was a delay of around two and a half years from when the design workshops were held and the actual trial beginning. This was due to discussions that took place within the wider multidisciplinary team regarding the most appropriate study design and developing the intervention. It is possible that this delay reduced the enthusiasm of the Care Co-ordinators and their willingness to complete the dental checklist with their service users.

It is not certain whether dental awareness training plus a dental checklist can lead to a clinically significant difference in the oral health behaviour of people with serious mental illness. Previous studies have made recommendations that relate to additional training for mental health professionals with regard to oral health care and the same conclusions can be drawn from this trial. The design may have played a factor in the low recruitment and follow up rate, but the enthusiasm and commitment to research and/or the topic of oral health care from the mental health professionals also seems to be a factor in the results of the trial. If mental health professionals are to be expected to be involved in any physical health care they should receive the appropriate level of training in order that they feel confident enough to be able to do so. The BSDH guidelines (2) recommended training on oral health care for mental health professionals, but it is possible that the brief information provided in this trial was simply not enough. Training used in future trials could also be delivered by a dentist or dental hygienist to increase its validity. The dental professionals would also be able to answer questions from the Care Co-ordinators about general oral health and questions specific to oral health care of people with serious mental illness better than a researcher.

### 5.6.2 New knowledge and lessons learned from the Three Shires Dental Trial

Although recruitment and missing data were problematic, there are important lessons that can be learned from this trial. The Care Co-ordinators did not appear to engage with the study. The trial was designed so that the intervention would be quick and easy to complete, this was done with the intention that it would then not be a problem for the Care Co-ordinators so that they would be able to

do it. It may be that too many steps were taken to make the trial 'too easy' and this had the opposite effect by then not being done. The Care Co-ordinators were consulted in the design process and the intervention itself should have taken only a few minutes to complete with each of their service users, but it was still not done, so lessons to be learned from this are that the Care Co-ordinators must actually be interested in a topic in order to have the enthusiasm to do it.

There were discussions during the dental awareness training sessions around what constituted good oral hygiene behaviour, for example one of the points on the oral hygiene information sheet handed to service users suggested not rinsing your mouth out after brushing your teeth, many questioned this and said that they always rinsed their own mouth out after brushing their teeth, so it is understandable that they may feel apprehensive instructing their service users not to do something that they do themselves. Improved dental awareness training could help with this. The large amount of missing data needs to be considered at the design stage as it was the design of the trial that accounted for a lot of the missing data at follow up. The sample size for an individually randomised trial would also be smaller and may be more achievable.

The next chapter will provide a summary of the findings from this thesis and also explore possible future directions for research involving training for mental health professionals regarding oral health care for people with serious mental illness.

## CHAPTER SIX. Discussion

### 6.1 Summary of findings

Chapter Two, a systematic review of 55 studies examining the prevalence of poor oral health and hygiene practices, dental treatment needs, and dental attendance of people with serious mental illness, was conducted to assess the extent to which people with serious mental illness brush their teeth, and attend dental appointments. This was deemed to be necessary as most systematic reviews concerning the oral health of people with serious mental illness have not included these outcomes and they are points that the BSDH guidelines recommended to be included as part of oral health monitoring for this population. This review found that the majority of participants did not practice good oral hygiene. They were less likely to brush their teeth than the general population, but for those who did brush their teeth, there was no great difference in the number of times a day that teeth were brushed compared to the general population. People with serious mental illness were more likely not to have seen a dentist for a longer period of time than the general population and they had more decayed teeth, more missing teeth, but fewer filled teeth, than the general population. Few people with serious mental illness were found to have healthy periodontal tissue; most required some form of dental treatment ranging from oral hygiene instruction to complex dental treatment for those with shallow pockets or deep pockets in their teeth.

As poor oral hygiene and infrequent dental visits have been shown to be associated with poor oral health, had this review found that the studies all showed that the participants brushed their teeth twice a day and visited a dentist every six months there would need to be other reasons why their oral health may be poor. This review supports previous research concluding that the oral health of people with serious mental illness is poor, but it also highlights the lack of professional dental care received by those with serious mental illness. The findings indicate that it may be possible to improve the oral health of people

with serious mental illness by designing an intervention that would raise awareness of the importance of good oral hygiene and regular dental visits.

Chapter Three, a narrative review of the knowledge and attitudes regarding oral health in populations with serious mental illness from service users, and mental health and dental professionals' perspectives, found that individuals with serious mental illness were more likely to have poor oral health due to neglecting their oral hygiene and because they did not attend regular dental appointments. Previous negative experiences at dental appointments or general dental anxiety prevented individuals with a mental illness from seeking help until they experience a dental emergency. This is similar to the general population. The majority of service users reported that support from mental health nurses was helpful, even though nurses tended to report feeling unconfident and inadequately trained to provide this care. There is little clarity of the role of mental health professionals surrounding the provision of oral health care in mental health settings from service users, dentists and the mental health professionals themselves. Dentists often sought help from mental health professionals who attended appointments with service users; this sometimes appeared to be perceived by the mental health nurses as outside of their role and dentists also reported having received a lack of training to treat people with serious mental illness.

Chapter Four, a systematic review of randomised controlled trials of interventions for improving the oral health of people with serious mental illness, identified four studies which all had such varied interventions and measured different outcomes that combining them in a meta-analysis was not possible. Two of the trials included in this review also received sponsorship and in one of the trials this involved supplying participants with electronic or manual toothbrushes. Although the toothbrushes appeared to improve the oral health of people with serious mental illness significantly, this would not be a practical solution in the majority of healthcare settings due to the cost involved. Some of the interventions involved an education element regarding oral hygiene

behaviour and the importance of oral health care for people with serious mental illness and these were found to improve oral health significantly. None of the studies monitored basic oral health outcomes like frequency of tooth brushing or attendance at dental appointments. A simple but effective intervention involving an element of education or advice that encouraged and monitored good oral hygiene behaviour that would also be sustainable within mental health settings could really make a difference.

Chapter Five, a pragmatic cluster randomised controlled trial of an oral health intervention for people with serious mental illness, described the methodology, findings and lessons to be learned from the trial. It involved 1074 service users from EIP teams in the East Midlands of England being randomised to receive either a dental intervention or standard care. The dental intervention involved completing a checklist with their Care Co-ordinator concerning their oral health and oral hygiene behaviour and the standard care simply involved continuing with their care plan for 12 months and then completing the checklist. At baseline only 271/550 service users randomised to the dental intervention group completed dental checklists. Only 98/271 (36.1%) of service users returned a completed dental checklist at the 12 month follow up and for those allocated to standard care 91/524 (17%) returned a completed dental checklist at the 12 month follow up. The majority of participants were lost from the trial for reasons unknown; despite multiple requests to Care Co-ordinators a checklist was not completed with some service users. Some participants were discharged from the service before a checklist could be completed. Data were still received 12 months after delivering the intervention for 189 participants but a large amount of data are missing. From the available data no significant differences were found; the checklist did not improve oral health behaviour in people with serious mental illness.

### 6.2 Implications for research

Future research should examine methods to incorporate oral hygiene knowledge and good oral hygiene behaviour into mental health nurses' training (104). Oral

health interventions that are aimed at mental health professionals, especially mental health nurses, should be thought of as just as important as the interventions that are aimed at patients with a serious mental illness. Dental hygienists have specialist knowledge in oral health and could provide training to mental health nurses to be able to provide better care for their patients' oral health (215). Improving the levels of oral health self-care and engagement with professional dental services would be of benefit to those with serious mental illness. The reasons why people with serious mental illness infrequently attend regular dental appointments should be explored further to allow steps to be taken to improve the quality of, and access to, care. Future research should focus on regularly monitoring the oral health of people with serious mental illness and explore how better to meet the needs of this population. Future research could also include more comprehensive oral health promotion programs with a standard care group and comparison group measuring the frequency of toothbrushing (58).

A recent trial that tested the effects of an oral hygiene education intervention on mental health nurses knowledge found that the nurses' oral hygiene knowledge significantly improved after the intervention ($p<0.001$) (215). This study used 20 items on oral hygiene knowledge that mental health nurses should know in order to care for their patients' oral health properly. There were seven questions on appropriate oral health care, seven questions on oral diseases, and six questions on smoking, alcohol, and drugs (Table 16). The mental health nurses also watched dental hygienists and researchers give a brief presentation on appropriate oral care, gingivitis, periodontal disease, and caries, the effects of smoking, alcohol, and drugs on oral health care. The adverse effects of psychotropic medications were also discussed and the dental hygienists demonstrated good oral hygiene behaviour and proper use of mouthwash, a tongue cleaner, and interdental cleaning aids. The presentation fitted into their daily routines. The mental health nurses who took part in this study did so on a voluntary basis, only half of the nurses who were invited actually agreed to participate. Some of the mental health nurses did try to motivate their patients

to care for their oral health and improve their oral hygiene behaviour, but many mental health nurses were rarely involved in encouraging better oral health for their patients with serious mental illness.

Table 16. Oral Hygiene Knowledge Items (215)

| |
|---|
| How often should one brush teeth daily for optimal oral hygiene? |
| Toothpaste should always contain fluoride. |
| What is the effect of fluoride? |
| Electric brushing is better than manual brushing. |
| What does preventive application in dental care mean? |
| What tools are used for cleaning between the teeth? |
| Two times mouth rinse is as effective as brushing two times per day? |
| Gingivitis is another name for . . . |
| Periodontitis is another name for . . . |
| What is the primary cause of gingivitis? |
| Periodontal disease is a . . . |
| What is another word for tooth decay? |
| Stress affects periodontitis. |
| What are the characteristics of gingivitis? |
| Every smoker has gingivitis, periodontitis, and caries. |
| By xerostomia we mean? |
| By hypo salivation we mean? |
| A side effect of antidepressants is…? |
| One side effect of antipsychotics is…? |

This intervention could be developed into a training package for mental health nurses. The basic dental awareness training that was given as part of the trial in Chapter Five may not have been detailed enough to provide the Care Co-ordinators with enough confidence in order to be able to complete the dental checklist with service users. If the dental awareness training session was delivered by a dentist or a dental hygienist it may also help with the feeling of

validity surrounding the intervention. A brief information booklet with instructions on good oral hygiene behaviour and specific information regarding side effects of medication and other issues for people with mental illness should be included so that it can be referred back to at a later date.

Whatever interventions are developed for use in future trials, a person-based approach (216) to the research should be used to improve the feasibility of the intervention during initial development. This will increase the possibility of a successful outcome when the intervention is evaluated in a trial. The person-based approach aims to "*ground the development of behaviour change interventions in a sensitive awareness of the perspective and lives of the people who will use them, obtained through mixed methods research and particularly iterative qualitative studies*" (217) (p.1). This approach takes into consideration the fact that different people in different situations may engage with the intervention in different ways, and that the relevance of some aspects may be more or less important to different people. With an intervention involving an oral health care training package for Care Co-ordinators, qualitative interviews with the Care Co-ordinators could be used early on to investigate how the intervention is perceived, whether or not their oral health knowledge is improving, and this could then be used to develop the intervention in line with the likes and dislikes of the target population.

### 6.3 Implications for clinical practice

It has been well established that most mental health professionals lack knowledge surrounding the oral health care of people with serious mental illness (17, 96, 109, 218). It is important that oral health care is established as a part of standard care. Mental health nurses should integrate oral health care into the daily care for individuals with serious mental illness.

Nurses need to receive proper training in providing oral health care to their patients, both during their nursing degree and postgraduate training. Mental health nurses also need to develop skills in motivating their patients to engage in

oral health care (215), they can then be better equipped to help their patients develop the ability to look after their oral health better. These professional skills can be used to help encourage the patients to care for their oral health themselves.

The need for physical health monitoring in the mental health setting should be incorporated into training for mental health professionals as the importance of oral health care for people with serious mental illness is still not recognised by many (17). Mental health professionals should receive training involving being able to identify and manage oral health risk factors like smoking, the oral side effects of psychotropic medication, and appropriate oral hygiene behaviour (2). Managing the oral health needs of patients should be officially incorporated into the role of mental health professionals (29), and they should support their patients when attending dental appointments.

Monitoring is generally well tolerated by patients and can be implemented in many different settings (17). People with serious mental illness should be given advice about their oral health as part of standard care from mental health professionals. The advice should include information on smoking, oral side effects of antipsychotics, and dietary advice including sugar-free lubrication to relieve symptoms of a dry mouth due to medication (17).

People with serious mental illness need encouragement and support to care for their oral health. Mental health professionals could compile a list of dental practices that are sympathetic to the needs of this vulnerable population. When an individual is discharged from a mental health service there should be procedures in place to ensure continuity of dental care (133). Training for dental professionals covering certain social and behavioural aspects of serious mental illness and possible oral side effects of antipsychotics can be provided.

## 6.4 Conclusions

Future randomised controlled trials should avoid cluster randomisation methods like that used in the trial in Chapter Five due to the potential large amount of missing data and problems that this can cause for analysis and interpretation of findings. An individually randomised design is often feasible or a design could incorporate Zelen's method of randomising participants but offering those allocated the intervention the opportunity to receive the control instead if they were not happy so as to increase compliance and decrease the number of participants who do not complete the follow up. Mental health nurses should receive focused training in order to deliver oral health care to their patients. The training needs to cover appropriate oral health care, how to recognise and manage oral diseases, as well as the impact that diet, smoking, alcohol, and drugs can have on oral health. Mental health nurses should be encouraged to support their patients with dental appointments as this has been found to be useful from both patient and dentists' perspectives. If nurses are to be trained in the understanding that psychotropic medication can lead to oral health problems like dry mouth it should also be measured as part of the trial outcomes. If recruitment is slow then telephone reminders may be more effective at improving recruitment rates than site visits. Financial incentives may also be of benefit.

This thesis presents findings of the extent of poor oral health on people with serious mental illness, knowledge and attitudes surrounding the oral health of people with serious mental illness from both professional and service user perspectives, an exploration of existing interventions and the design, implementation and findings from a pragmatic cluster randomised controlled trial of an oral health intervention for people with serious mental illness. Although the dental checklist was not found to change oral health behaviour of people with serious mental illness significantly, findings from the trial can help to shape future research in this still under-researched area. Future research should focus on improving mental health professionals' knowledge and confidence in managing the oral health of their patients.

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**APPENDIX**

## Appendix 1. Ethics committee approval letter

2nd Re-Issue Favourable Opinion Letter 13 December 2011 - to include Poster V1 dated 01 April 2011 as previously missing.

NHS
Health Research Authority

**NRES Committee East Midlands - Nottingham 1**
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839390 (Direct Line)
Facsimile: 0115 9123300

12 August 2011

Professor Clive E Adams
Chair Mental Health Services Research
University of Nottingham
Sir Colin Campbell Building
Innovation Park
Triumph Road
NG7 2TU

Dear Professor Adams

| | |
|---|---|
| **Study title:** | **Monitoring oral health for young people with serious mental illness: A cluster randomised controlled trial** |
| **REC reference:** | **11/EM/0205** |
| **Protocol number:** | **Final 1.2** |

Thank you for your letter of 13 July 2011, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the sub-committee.

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Ethical review of research sites**

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

***Conditions of the favourable opinion***

*The favourable opinion is subject to the following conditions being met prior to the start of the study.*

*Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.*

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations*

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

| *Document* | *Version* | *Date* |
|---|---|---|
| Advertisement | "promoting healthy teeth and gums" oral hygiene info sheet 1 | 01 April 2011 |
| Advertisement - Poster | 1 | 01 April 2011 |
| Covering Letter | Email | 21 July 2011 |
| Evidence of insurance or indemnity | | 23 May 2011 |
| Investigator CV | | |
| Letter from Sponsor | | 23 May 2011 |
| Letter of invitation to participant | Email | 01 April 2011 |
| Other: List of Dental Advisory Group Members | | |
| Participant Consent Form: P1 - 12 months OIDP | 3 | 11 August 2011 |
| Participant Consent Form: M1 - Manager | 3 | 11 August 2011 |
| Participant Consent Form: P2 Implementation Service User | 3 | 11 August 2011 |
| Participant Consent Form: S1 - Care Coordinator | 3 | 11 August 2011 |
| Participant Consent Form: S2 Implementation | 3 | 11 August 2011 |
| Participant Consent Form: S4 Care Coordinator | 3 | 11 August 2011 |
| Participant Consent Form: P4 Service User Contact Dentist | 3 | 11 August 2011 |
| Participant Information Sheet: Manager - M1 Pre-Randomisation Agreement | 3 | 11 August 2011 |
| Participant Information Sheet: Service User P1 - 12 months | 3 | 11 August 2011 |
| Participant Information Sheet: P2 Implementation - Service User | 3 | 11 August 2011 |
| Participant Information Sheet: P4 Service User - Contact Dentist | 3 | 11 August 2011 |
| Participant Information Sheet: S1 Care Coordinator - Initial Intervention | 3 | 11 August 2011 |
| Participant Information Sheet: S2 Implementation - Staff | 3 | 11 August 2011 |
| Participant Information Sheet: S4 - Care Coordinator Control 12 months | 3 | 11 August 2011 |
| Protocol | Draft 21/Final 1.2 | 10 August 2011 |
| Questionnaire: Oral Impacts on Daily performance (OIDP) | | |
| Questionnaire: Three Shires Dental checklist | 1 | 01 April 2011 |

| | | |
|---|---|---|
| REC application | | 23 May 2011 |
| Response to Request for Further Information | | 13 July 2011 |

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**After ethical review**

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

| | |
|---|---|
| **11/EM/0205** | **Please quote this number on all correspondence** |

With the Committee's best wishes for the success of this project

Yours sincerely

P. Wheat

**Mr Robert Johnson**
**Chair**

Email: trish.wheat@nottspct.nhs.uk

*Enclosures:* "After ethical review – guidance for researchers"

*Copy to:* *Mr Paul Cartledge – University of Nottingham*

*R & D Dept. - Nottinghamshire Healthcare NHS Trust*

*Hannah Jones – Research Assessment*

## Appendix 2. Ethics committee approval letter for amendment

NHS
Health Research Authority

**NRES Committee East Midlands - Nottingham 1**
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 0115 883 9390

18 December 2012

Professor Clive E Adams
Sir Colin Campbell Building
Innovation Park
Triumph Road
NG7 2TU

Dear Professor Adams,

| | |
|---|---|
| **Study title:** | **Monitoring oral health for young people with serious mental illness: A cluster randomised controlled trial** |
| **REC reference:** | **11/EM/0205** |
| **Protocol number:** | **10105** |
| **Amendment number:** | **Modified Amendment 3** |
| **Amendment date:** | **14 December 2012** |
| **IRAS project ID:** | **54878** |

Thank you for submitting the above amendment, which was received on 14 December 2012. It is noted that this is a modification of an amendment previously rejected by the Committee (our letter of 12th December 2012 refers).

The modified amendment has been considered on behalf of the Committee by the Chair.

**Ethical opinion**

There were no Ethical issues

I am pleased to confirm that the Committee has given a favourable ethical opinion of the modified amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved are:

| Document | Version | Date |
|---|---|---|
| Letter to Dentist | 2 | 13 December 2012 |
| Participant Consent Form: Dentist Consent Form | 2 | 13 December 2012 |
| Modified Amendment | | |
| Oral health form | 2 | 13 December 2012 |
| Participant Information Sheet: Dentist information sheet | 2 | 13 December 2012 |
| Covering Letter | Letter to Ethics Committee- modification for amendment 2 | 13 December 2012 |

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

| 11/EM/0205: | Please quote this number on all correspondence |
|---|---|

Yours sincerely,

**Mr Robert Johnson**
**Chair**

E-mail: NRESCommittee.EastMidlands-Nottingham1@nhs.net

*Copy to:* *Ms Emma Pearson, Nottinghamshire Healthcare NHS Trust*
*Mr Paul Cartledge, University of Nottingham*

## Appendix 3. Ethics committee approval letter for amendment

NHS
Health Research Authority

**NRES Committee East Midlands - Nottingham 1**
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 0115 883 9390

13 August 2013

Professor Clive E Adams
University of Nottingham
Sir Colin Campbell Building
Innovation Park
Triumph Road
NG7 2TU

Dear Professor Adams,

| | |
|---|---|
| **Study title:** | **Monitoring oral health for young people with serious mental illness: A cluster randomised controlled trial** |
| **REC reference:** | **11/EM/0205** |
| **Protocol number:** | **10105** |
| **Amendment number:** | |
| **Amendment date:** | **19 July 2013** |
| **IRAS project ID:** | **54878** |

The above amendment was reviewed at the meeting of the Sub-Committee held on 13 August 2013.

**Ethical opinion**

There were no Ethical issues

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

| Document | Version | Date |
|---|---|---|
| Protocol | 25 | 18 July 2013 |
| Covering Letter | | 18 July 2013 |
| Participant Information Sheet: P1 service user information sheet 12 months | 4 | 18 July 2013 |
| Notice of Substantial Amendment (non-CTIMPs) | | 19 July 2013 |
| Participant Information Sheet: P4 service user information sheet contact dentist | 4 | 18 July 2013 |

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

| | |
|---|---|
| **11/EM/0205:** | **Please quote this number on all correspondence** |

Yours sincerely,

**Reverend Keith Lackenby**
**Vice Chair**

E-mail: NRESCommittee.EastMidlands-Nottingham1@nhs.net

*Enclosures:* *List of names and professions of members who took part in the review*

*Copy to:* *Mrs Emma Pearson,*
*Ms Angela Shone*
*Hannah Jones*

**NRES Committee East Midlands - Nottingham 1**

**Attendance at Sub-Committee of the REC meeting on 13 August 2013**

| *Name* | *Profession* | *Capacity* |
|---|---|---|
| Reverend Keith Lackenby | Lay member | Lay Plus |
| Mr Jon Merrills | Barrister / Pharmacist | Expert |

**Also in attendance:**

| *Name* | *Position (or reason for attending)* |
|---|---|
| Miss Rebecca Morledge | Assistant Coordinator |

## Appendix 4. Nottinghamshire Healthcare NHS Trust approval letter

positive

Nottinghamshire Healthcare NHS
NHS Trust
Positive about mental health and learning disability

Research Management and Governance
Institute of Mental Health
2nd Floor, Duncan MacMillan House
Porchester Road
Nottingham

E-mail: emma.pearson@nottshc.nhs.uk
Direct Line: ext 10661 / 10663

Tel: 0115 969 1300

Local Ref: CSP/20/12/11
Rec ID: 11/EM/0205

Date: 20th December 2011

Professor Clive Adams
University of Nottingham
Sir Colin Campbell Building
Innovation Park
Triumph Road
Nottingham NG7 2TU

Dear Prof Adams

I am writing to confirm that NHS permission for research has been granted for the following study.

**Title:** Monitoring oral health for young people with serious mental illness: a cluster randomised controlled trial

**Sites within Nottinghamshire Healthcare NHS Trust that have been given NHS permission:**

- Early Intervention in Psychosis Teams within Nottinghamshire Healthcare NHS Trust

**NHS permission for the above research has been granted on the basis described in the application form, protocol, supporting documentation**

**Start Date:** 20/12/2011 **End Date:** 31/12/2013

**Study Outline:**

This is a NIHR CLARHC funded mental health cluster randomised controlled trial regarding an intervention in dental health and whether the intervention group will attend a dentist more frequently in a year. Potential participants will be approached through the Care Co-ordinators for the Early Intervention in Psychosis (EIP) teams. The expected sample size for Nottinghamshire Healthcare NHS Trust will be 200.

Randomisation will be undertaken by Nottingham CTU. Staff in the teams allocated to the intervention group will receive dental awareness training (30-60 minutes). A dental checklist will be completed at the beginning of the year for those in the intervention group. A non-obligatory information leaflet will be given to the service user to act as an oral health prompt (intervention) to the intervention group. 12 months following this, both the intervention and control groups will be asked to complete the dental checklist. The control group will receive the information leaflet (intervention) at the end of the study so that all study participants receive the intervention (as per REC favourable opinion).

At the 12 month point, participants will be asked if they wish to be contacted for further follow up. If not, their participation in the study is finished. If further follow up is consented, service users from both the standard care and intervention groups will be asked to consent to

complete an Oral Impacts on Daily Performance (OIDP) measure (taking approximately 20 minutes) and includes QoL. An implementation study at the end of the 12 month period may involve approximately 20 semi-structured interviews with consenting staff and service users to review the research process and evaluation of the application to practice.

Please note that Nottingham Healthcare NHS Trust is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research and requesting the completion of a brief progress report every 6 months.

You can now proceed with your study in accordance with the agreed protocol. Please keep this letter with you during the course of your research to confirm that you have Directorate and RMG Department approval, to gain access to the areas where your research is taking place.

If you or others have concerns please contact the RMG department on 0115 9691300 ext 10661 or by email to emma.pearson@nottshc.nhs.uk

We wish you well with your work.

Yours sincerely

Dr Peter Miller
Medical Director
Nottinghamshire Healthcare NHS Trust

Cc:
Sponsor: The University of Nottingham

**Conditions of Trust approval are as follows.**

1. All members of the research team should familiarise themselves with all relevant policies and procedures, including the Trust policy GG/CG/04 – staff conducting, hosting or collaborating in research (note, currently being revised).

2. The Chief Investigator, and all other members of the research team, should comply with any regulations applicable to the study, including, but not limited to: The NHS Research Governance Framework for Health and Social Care (2005), The Declaration of Helsinki (2000), The UK Medicines for Human Use (Clinical Trials) Regulations (2004), ICH Good Clinical Practice guidelines (1997), The Human Tissue Act (2004), The Data Protection Act (1998), The Mental Capacity Act (2005).

3. The Chief Investigator should ensure that all members of the research team are suitably qualified and experienced, and adequately supervised. This should include training in informed consent procedures and GCP, where necessary.

4. Research governance should be notified within the same timeframe of notifying REC of any major changes to the study, which may include changes to the team, requiring honorary contracts or letters of access to be issued, changes to timescales or changes in procedures.

a. Any changes in the protocol or documentation should be approved by the ethics committee and research governance.

5. Care professionals should be informed of their patients' participation in the research.

6. The protocol should be adhered to; any deviations should be notified to research governance.

7. Suitable arrangements for archiving should be made in accordance with the guidelines of the sponsor, and research governance should be kept informed of any changes or failures in archiving arrangements, including failures in safe preservation of electronic data. Failure to report such losses will result in disciplinary investigation of Trust staff, and a disciplinary enquiry of external researchers, which could result in the rescinding of rights to carry research in the Trust.

## Appendix 5. Derbyshire Healthcare NHS Foundation Trust approval letter

Derbyshire Healthcare NHS
NHS Foundation Trust

Mental Health Research Unit
Kingsway House
Kingsway
Derby
DE22 3LZ

Tel: (01332) 623579
Fax: (01332) 623576
Email: Rubina.Reza@Derbysnet.nhs.uk

29th March 2012

Professor Clive Adams
CLAHRC NDL,
Sir Colin Campbell Building
Innovation Park
Triumph Road
University of Nottingham
Nottinghamshire
NG7 2TU

Dear Professor Adams

I am writing to inform you that the Derbyshire Healthcare NHS Foundation Trust Clinical Research Committee has reviewed and approved the following study:

| | |
|---|---|
| **Title:** | CLAHRC NDL The three shires early intervention dental trial: A real-world cluster randomised controlled trial |
| **REC ref:** | 11/EM/0205 |
| **CSP ref:** | 54878/T |
| **Area:** | Early Interventions Services |
| **Start date:** 29/03/2012 | **End date:** 30/09/2013 |

**Documents Reviewed:**

1. 54878 DMH governance report FINAL 19.03.2012
2. Derbyshire SSI form Signed, 04/01/2012
3. Protocol v1.2 10 August 2011
4. NHS RD form (unsigned)

**Letter of Access:**
1. Hannah Jones Letter of Access issued on 14/09/2011

As part of our monitoring requirements, we will ask you for a progress report six months after the start of your study, and every six months as applicable. We will also ask you for a short summary of your research findings once the study is complete to assist in the dissemination process within the Trust.

You can now proceed with your study in accordance with the agreed protocol and the Research Governance Framework. Please notify us immediately of any adverse events or changes to the protocol.

If you require any further information please do not hesitate to contact me.

Yours sincerely

Rubina Reza
Research and Clinical Audit Manager

On behalf of Dr John Sykes and the Clinical Research Committee

**Approved documents received:**

Protocol v1.2 10 August 2011
Participant Information Sheet: Service User P1 – 12 months v3 August 2011
Participant Consent Form: P1 – 12 month OIDP v3 August 2011
Participant Information Sheet: P2 Implementation – Service User v3 August 2011
Participant Consent Form: P2 Implementation – Service User v3 August 2011
Participant Information Sheet: P4 Service User – Contact Dentist v3 August 2011
Participant Consent Form: P4 Service User – Contact Dentist v3 August 2011
Participant Information Sheet: S1 Care Coordinator – Initial Intervention v3 August 2011
Participant Consent Form: S1 Care Coordinator v3 August 2011
Participant Information Sheet: S2 Implementation – Staff v3 August 2011
Participant Consent Form: S2 Implementation – Staff v3 August 2011
Participant Information Sheet: S4 – Care Coordinator Control 12 months v3 August 2011
Participant Consent Form: S4 Care Coordinator v3 August 2011
Participant Information Sheet: Manager – M1 pre-randomisation agreement v3 August 2011
Participant Consent Form: M1 Manager v3 August 2011
Questionnaire: Oral impacts on Daily Performance (OIDP)
Questionnaire: Three Shires Dental Checklist v1 April 2011
Advertisement: Oral hygiene information sheet v1 April 2011
Email approach to implementation participant V1 April 2011
Dental Poster V1, April 2011

## Appendix 6. Lincolnshire Partnership NHS Foundation Trust approval letter

Lincolnshire Partnership NHS
NHS Foundation Trust

Ref:11/EM/0205 (CSP:54878)
Date: 25th January 2011

Professor Clive Adams
CLAHRC - NDL
Sir Colin Campbell Building
University of Nottingham
Innovation Park
Triumph Road
NOTTINGHAM
NG7 2TU

Research and Effectiveness Team
Trust Headquarters
Unit 9, The Point
Lions Way
SLEAFORD
Lincolnshire
NG34 8GG

Tel: 01529 222206
Fax: 01529 222226

Dear Professor Clive Adams

**Study title: Dental care of young people with serious mental illness. (Monitoring oral health for young people with serious mental illness: A real – world cluster randomized controlled trial)**
**Chief Investigator name: Professor Clive Adams**
**Sponsor name: University of Nottingham**
**REC number: 11/EM/0205**
**Date of permission: 25th January 2012**

List of all site(s) for which NHS permission for research is given: **Lincolnshire Partnership NHS Foundation Trust**

NHS permission for the above research has been granted by Lincolnshire Partnership NHS Foundation Trust on the basis described in the application form, protocol and supporting documentation.

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, ICH GCP and NHS Trust policies and procedures (available at http://www.lpt.nhs.uk/).

Permission is only granted for the activities for which a favourable opinion has been given by the REC [and which have been authorised by the MHRA]

The research sponsor or the Chief Investigator, or the local Principal Investigator at a research site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.

The Research and Effectiveness office should be notified, at the address above, that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The Research and Effectiveness Office should be notified within the same time frame of notifying the REC and any other regulatory bodies.

Any research carried out by a Trust employee with the knowledge and permission of the employing organisation will be subject to NHS indemnity. NHS indemnity provides indemnity against clinical risk arising from negligence through the Clinical Negligence Scheme for Trusts (CNST). Further details can be found at Research in the NHS: Indemnity arrangements (Department of Health 2005).

All amendments (including changes to the local research team) need to be submitted in accordance with guidance in IRAS.

Please inform the Research and Effectiveness department of any changes to study status.

Please note that the NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research.

We are pleased to inform you that you may now commence your research. Please retain this letter to verify that you have Trust permission to proceed. We wish you every success with your work.

Yours sincerely

Dianne Tetley

**Dianne Tetley**
**Assistant Director Research and Effectiveness**
**Lincolnshire Partnership NHS Foundation Trust**

Cc Sponsor Paul Cartledge – University of Nottingham
Study Coordinator Hannah Jones

Enc: Data Protection Guidance on the transportation of personal identifiable data

**Appendix 7. Manager information sheet**

**Manager information sheet**

**The three shires early intervention dental trial**

We would like to invite your service to take part in a research study whose purpose is to improve the dental care of young people with mental health problems. To help you decide whether you wish your service to participate in the study, please take a moment to read this information sheet, to understand why the research is being done and how it could benefit service users. We also recommend that you talk to others about the study if you wish, or ask a member of the research team for more information.

**What is the purpose of the study?**

Oral health problems are not well recognized by mental health professionals and when treatment is accessed people with mental illnesses generally experience barriers to treatment. The purpose of this study is to improve the oral care of people with mental illness who are receiving treatment and care from Early Intervention teams in Derbyshire, Nottinghamshire & Lincolnshire. We wish to compare the effectiveness of two different approaches to improving the oral health of young people experiencing mental health problems.

**Why have I been invited?**

You have been invited to take part because you are the Manager of one of the Early Intervention teams in Nottinghamshire, Derbyshire & Lincolnshire which have been selected to take part in this study. Should you agree to take part in the study, we will ask you to sign a consent form by meeting with the researcher (Hannah Jones), who will also be able to answer any questions that you may have.

**Do I have to take part?**

Participation in this study is entirely voluntary. If you agree to take part, we will ask you to sign a consent form. If you change your mind, you are free to withdraw your team at any point, without giving a reason.

**What will I have to do if I participate?**

Before we begin our study and prior to randomisation of the teams we want you to grant permission, for the researcher (Hannah Jones), to get information about the form of the team and the Care Co-ordinators. We will also work with team secretaries asking them to create a list of eligible service users who can participate in the study and a cross coding sheet (CCS) by which each service user is given an anonymous study number. This is a trial of monitoring data that are thought to be part of good care by these care teams and we do not envisage collecting personal data traceable back to the service user for the key outcomes. Information will be distributed to the teams for posting in the waiting rooms informing of the ongoing Dental monitoring study.

**What exactly will happen during the study?**

It is not always clear which is the best treatment for patients. As a result, we need to compare different treatments to find out which is the most effective. To do this we put people into groups, chosen at random, and give each group a different treatment. The results from the groups are then compared to see if one treatment is better than others. In this research there are two groups; in one group staff will receive dental awareness training, complete the dental health checklist and distribute oral health packs to service users, while the other group will receive care as usual.

One year later care coordinators from both groups of the study will complete the dental health checklist. At this time service users in both groups will be asked by their care coordinator if they can be approached by a researcher and asked to complete an Oral Impacts on Daily Performance (OIDP) measure. The OIDP measures health related quality of life by assessing how the service user has

changed their behaviour because of their oral health. The questionnaire takes about 20 minutes to administer and will be completed by a researcher, not the care coordinator.

**What are the possible benefits of taking part?**

Although we cannot guarantee the study will benefit all individual service users, however, we hope the information we get from this study will help improve the oral health of young people with mental health problems.

**Expenses and payments**

Participants will not be paid to participate in the trial. There should be no associated costs as a result of this trial. If travel expenses do occur as a result of participation they will be reimbursed.

**What are the possible disadvantages of taking part?**

Participating in this research should not cause any inconvenience, discomfort or distress. Some of the questions your team ask service users may be quite personal but any information shared will be kept strictly confidential and anonymous.

**What happens when the research study stops?**

Your team will provide care as usual to service users.

**What if relevant new information becomes available?**

The Investigator will inform you of any relevant information that becomes available during the course of the study and will discuss with you whether you wish to continue with the study. If applicable you will be asked to sign revised consent forms.

**What will happen if I don't want to carry on with the study?**

Your team's participation is voluntary and you are free to withdraw at any time, without giving a reason. If you withdraw then the information collected so far cannot be erased and this information may still be used in project analysis.

**What if there is a problem?**

If you have any questions, concerns, or complaints about this study, you can contact any of the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally you can do this by contacting NHS complaints. Details can be obtained from your Trust.

**Will participation in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Any information you share will be kept strictly confidential and anonymous. This means that the interview data will only be accessible to the research team and you will not be recognisable in research reports or publications. The only exception to this would be if during the interview you were to disclose anything which might cause risk to others or to the organisation, for example, bad practice. In those rare circumstances, we would disclose essential information only to a third party, and would ideally discuss with you first. All data collected will be anonymised and handled securely, according to the 1998 Data Protection Act and the University of Nottingham's own guidelines, and stored for seven years, before being destroyed safely.

**What will happen to the results of the research study?**

At the end of this study, a summary of our findings will be posted on the website of the Institute of Mental Health (www.institutemh.org.uk). We will also write papers for conferences and journal publications. We can also provide verbal and written feedback to staff working in Early Intervention Teams in Nottinghamshire, Derbyshire & Lincolnshire.

**Who is organising and funding the research?**

This study is funded by the National Institute for Health Research via the Collaboration for Leadership in Applied Health Research and Care - Nottinghamshire, Derbyshire and Lincolnshire (CLAHRC-NDL). More information about this programme can be found at: www.clarhc-ndl.nihr.ac.uk. The chief investigator and researcher are both based at the University of Nottingham.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Nottinghamshire 1 Research Ethics Committee 11/EM/0205.

**Further information and contact details**

If you decide to take part in this study you will be given a copy of this information sheet and a copy of the consent form. If you would like more information about this research project or have any questions or concerns, please contact:

**Researcher:** Hannah Jones. Tel: 0115 823 1267 or email: Hannah.Jones@nottingham.ac.uk

**Chief Investigator:** Professor Clive E Adams. Tel: 0115 82 31 274 or email: clive.adams@nottingham.ac.uk

**Appendix 8. Manager consent form**

**Manager consent form**

**Title of Study:** The three shires early intervention dental trial

**REC ref:** 11/EM/0205

**Name of Researchers:**

**Name of Participant:**

Please initial box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my employment and legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential, except where if during the interview I was to disclose anything which might cause risk to others or to the organisation, for example, bad practice. In those rare circumstances, essential information only would be disclosed to a third party, and this would be discussed with me first. ☐
4. I agree to grant permission to collect pre-trial data for our EIP team. ☐
5. I agree to take part in the above study. ☐

| Name of Participant | Date | Signature |
|---|---|---|
| Name of person taking consent | Date | Signature |

## Care Coordinator Information sheet

**The three shires early intervention dental trial**

We would like to invite you to take part in a research study whose purpose is to improve the dental care of young people with mental health problems. To help you decide whether you wish to participate in the study, please take a moment to read this information sheet, to understand why the research is being done and how it could benefit service users. We also recommend that you talk to others about the study if you wish, or ask a member of the research team for more information.

**What is the purpose of the study?**

Oral health problems are not well recognized by mental health professionals and when treatment is accessed people with mental illnesses generally experience barriers to treatment. The purpose of this study is to improve the oral care of people with mental illness who are receiving treatment and care from Early Intervention teams in Derbyshire, Nottinghamshire & Lincolnshire. We wish to compare the effectiveness of two different approaches to improving the oral health of young people experiencing mental health problems.

**Why have I been invited?**

You have been invited to take part because you are a care coordinator in one of the Early Intervention teams which have been randomised to get the active intervention in this trial. Should you agree to take part in the study, we will ask you to sign a consent form by meeting with the researcher (Hannah Jones), who will also be able to answer any questions that you may have.

**Do I have to take part?**

Participation in this study is entirely voluntary. If you agree to take part, we will ask you to sign a consent form. If you change your mind, you are free to withdraw at any point, without giving a reason.

**What will I have to do if I participate?**

You will receive some dental awareness training (DAT). This consists of a 30 minute presentation led by a researcher who will outline the nature of the research and provide instruction on how to complete the dental health checklist. The DAT will take place at a convenient location for you and there will be an opportunity to ask questions about any aspect of the study. We will then ask you to distribute a dental information pack and complete the dental health checklist with each service user on your caseload. This is a very simple check list for monitoring oral health. It does not specifically encourage advice or patterns of behaviour, but it does alert the care coordinator to these aspects of physical healthcare. It should take no longer than ten minutes to distribute the packs and complete the checklist. One copy of the checklist will go into the service users CPA documents, one copy will be given to the service user if they want it, and one copy will be sent to the research team (envelope supplied). One year later you will be asked to complete the dental health checklist again.

**What exactly will happen during the study?**

It is not always clear which is the best type of care for patients. As a result, we need to compare different types of care to find out which is the most effective. To do this we put people into groups, chosen at random, and give each group a different type of care. The results from the groups are then compared to see if one type of care is better than others. In this research there are two groups; in one group staff will receive dental awareness training, complete the dental health checklist and distribute oral health packs to service users, while the other group will receive care as usual.

One year later care coordinators from both groups of the study will complete the dental health checklist. At this time service users in both groups will be asked by their care coordinator if they can be approached by a researcher and asked to complete an Oral Impacts on Daily Performance (OIDP) measure. The OIDP measures health related quality of life by assessing how the service user has changed their behaviour because of their oral health. The questionnaire takes

about 20 minutes to administer and will be completed by a researcher, not the care coordinator.

**What are the possible benefits of taking part?**

Although we cannot guarantee the study will benefit all individual service users, however, we hope the information we get from this study will help improve the oral health of young people with mental health problems.

**Expenses and payments**

Participants will not be paid to participate in the study. There should be no associated costs as a result of this study. If travel expenses do occur as a result of participation they will be reimbursed.

**What are the possible disadvantages of taking part?**

Participating in this research should not cause you any inconvenience, discomfort or distress. Some of the questions you ask service users may be quite personal but any information you share will be kept strictly confidential and anonymous.

**What happens when the research study stops?**

You will provide care as usual to service users.

**What if relevant new information becomes available?**

The Investigator will inform you of any relevant information that becomes available during the course of the study and will discuss with you whether you wish to continue with the study. If applicable you will be asked to sign revised consent forms.

**What will happen if I don't want to carry on with the study?**

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (contact numbers below). If you remain unhappy and wish to complain formally you can do this by contacting NHS complaints, details can be obtained from your Trust.

**Will my participation in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Any information you share will be kept strictly confidential and anonymous. This means that the interview data will only be accessible to the research team and you will not be recognisable in research reports or publications. The only exception to this would be if during the interview you were to disclose anything which might cause risk to others or to the organisation, for example, bad practice. In those rare circumstances, we would disclose essential information only to a third party, and would ideally discuss with you first. All data collected will be anonymised and handled securely, according to the 1998 Data Protection Act and the University of Nottingham's own guidelines, and stored for seven years, before being destroyed safely.

**What will happen to the results of the research study?**

At the end of this study, a summary of our findings will be posted on the website of the Institute of Mental Health (www.institutemh.org.uk). We will also write papers for conferences and journal publications. We can also provide verbal and written feedback staff working in Early Intervention Teams in Nottinghamshire, Derbyshire & Lincolnshire.

**Who is organising and funding the research?**

This study is funded by the National Institute for Health Research via the Collaboration for Leadership in Applied Health Research and Care -

Nottinghamshire, Derbyshire and Lincolnshire (CLAHRC-NDL). More information about this programme can be found at: www.clarhc-ndl.nihr.ac.uk. The chief investigator and researcher are both based at the University of Nottingham.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by (Nottingham 1) Research Ethics Committee.

**Further information and contact details**

If you decide to take part in this study you will be given a copy of this information sheet and a copy of the consent form which you have signed. If you would like more information about this research project or have any questions or concerns please contact:

**Researcher:** Hannah Jones, CLAHRC, Division of Psychiatry**,** University of Nottingham Innovation Park, NG7 2RD Tel: 0115 823 1267 or email: Hannah.Jones@nottingham.ac.uk

If you are unable to get through to Hannah Jones, you can also contact our administrator Shirley Woolley on 0115 823 2472 or by email: Shirley.Wooley@nottingham.ac.uk

**Chief Investigator:** Professor Clive E Adams, Division of Psychiatry**,** University of Nottingham, University Park, Nottingham, NG7 2RD. Tel: 0115 82 31 287 email: clive.adams@nottingham.ac.uk

## Appendix 10. Care Co-ordinator consent form

### Care Co-ordinator consent form

**Title of Study:** The three shires early intervention dental trial

**REC ref:** 11/EM/0205

Please initial box

**Name of Researchers**:

**Name of Participant:**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential, except where if during the interview I was to disclose anything which might cause risk to others or to the organisation, for example, bad practice. In those rare circumstances, essential information only would be disclosed to a third party, and this would be discussed with me first. ☐
4. I agree to complete the oral health checklist. ☐
5. I agree for follow-up data to be collected 12 months later. ☐
6. I agree to take part in the above study. ☐

| Name of Participant | Date | Signature |
|---|---|---|
| Name of person taking consent | Date | Signature |

**Appendix 11. Service user information sheet for OIDP outcome**

**Service user information sheet**

**The three shires early intervention dental trial**

We would like to invite you to take part in a research study whose purpose is to improve the dental care of young people with mental health problems. To help you decide whether you wish to participate in the study, please take a moment to read this information sheet, to understand why the research is being done and how it could benefit service users. We also recommend that you talk to others about the study if you wish, or ask a member of the research team for more information.

**What is the purpose of the study?**

Oral health problems are not well recognized by mental health professionals and when treatment is accessed people with mental illnesses generally experience barriers to treatment. The purpose of this study is to improve the oral care of people with mental illness who are receiving treatment and care from Early Intervention teams in Derbyshire, Nottinghamshire & Lincolnshire. We wish to compare the effectiveness of two different approaches to improving the oral health of young people experiencing mental health problems.

**Why have I been invited?**

You have been invited to take part because you have been identified by your care coordinator as someone receiving care from one of the Early Intervention teams in Nottinghamshire, Derbyshire & Lincolnshire. Should you agree to take part in the study, we will ask you to sign a consent form by the researcher who will also be able to answer any questions that you may have.

**Do I have to take part?**

Participation in this study is entirely voluntary. If you agree to take part, we will ask you to sign a consent form. If you change your mind, you are free to withdraw at any point, without giving a reason.

**What will I have to do if I participate?**

You will be asked to meet with the researcher on one occasion. During this meeting, which lasts approximately 30 minutes the researcher will complete a paper-based questionnaire with you.

You can choose where these meetings take place - at the community mental health site that you visit, at your home or at the University of Nottingham premises, depending on which is convenient for you. The researcher will ask you questions about any difficulties or problems you have had with your mouth and teeth in the past six months. You may also be approached to take part in interviews for subsequent elements of the study, but you do not have to agree to this.

It is not always clear which is the best type of care for service users. As a result, we need to compare different types of care to find out which is the most effective. To do this we put people into groups, chosen at random, and give each group a different type of care. The results from the groups are then compared to see if one type of care is better than others. In this research there are two groups; in one group staff receive dental awareness training, complete the dental health checklist and distribute oral health packs to service users, while the other group receive care as usual.

One year later care coordinators from both groups of the study complete the dental health checklist. At this time service users in both groups are asked by their care coordinator if they can be approached by a researcher and asked to complete an Oral Impacts on Daily Performance (OIDP) measure. The OIDP measures health related quality of life by assessing how the service user has

changed their behaviour because of their oral health. The questionnaire takes about 20 minutes to administer and is completed by a researcher, not the care coordinator. Some service users, at random, will then be approached by the researcher to provide more information about their dental health.

**What exactly will happen during the study?**

It is not always clear which is the best type of care for service users. As a result, we need to compare different types of care to find out which is the most effective. To do this we put people into groups, chosen at random, and give each group a different type of care. The results from the groups are then compared to see if one type of care is better than others. In this research there are two groups; in one group staff receive dental awareness training, complete the dental health checklist and distribute oral health packs to service users, while the other group receive care as usual.

One year later care coordinators from both groups of the study complete the dental health checklist. At this time service users in both groups are asked by their care coordinator if they can be approached by a researcher and asked to complete an Oral Impacts on Daily Performance (OIDP) measure. The OIDP measures health related quality of life by assessing how the service user has changed their behaviour because of their oral health. The questionnaire takes about 20 minutes to administer and is completed by a researcher, not the care coordinator. Some service users, at random, will then be approached by the researcher to provide more information about their dental health.

**What are the possible benefits of taking part?**

Although we cannot guarantee the study will benefit all individual service users, however, we hope the information we get from this study will help improve the oral health of young people with mental health problems.

**Expenses and payments**

Participants will not be paid to participate in the trial. There should be no associated costs as a result of this trial. If travel expenses do occur as a result of participation they will be reimbursed.

**What are the possible disadvantages of taking part?**

Participating in this research should not cause you any inconvenience, discomfort or distress. Some of the questions we ask may be quite personal but any information you share will be kept strictly confidential and anonymous.

**What happens when the research study stops?**

You will receive ongoing support from your care coordinator.

**What if relevant new information becomes available?**

The Investigator will inform you of any relevant information that becomes available during the course of the study and will discuss with you whether you wish to continue with the study. If applicable you will be asked to sign revised consent forms.

**What will happen if I don't want to carry on with the study?**

Your participation is voluntary and you are free to withdraw at any time, without giving a reason and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in project analysis.

**What if there is a problem?**

If you have any questions, concerns, or complaints about this study, you can contact any of the researchers (contact details below) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting NHS complaints. Details can be obtained from your Trust.

**Will my participation in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Any information you share will be kept strictly confidential and anonymous. This means that the interview data will only be accessible to the research team and you will not be recognisable in research reports or publications. The only exception to this would be if during the interview you were to disclose anything which might cause risk to others or to the organisation, for example, bad practice. In those rare circumstances, we would disclose essential information only to a third party, and would ideally discuss with you first. All data collected will be anonymised and handled securely, according to the 1998 Data Protection Act and the University of Nottingham's own guidelines, and stored for seven years, before being destroyed safely.

**What will happen to the results of the research study?**

At the end of this study, a summary of our findings will be posted on the website of the Institute of Mental Health (www.institutemh.org.uk). We will also write papers for conferences and journal publications. We can also provide verbal and written feedback for service users in Early Intervention Teams in Nottinghamshire, Derbyshire & Lincolnshire.

**Who is organising and funding the research?**

This study is funded by the National Institute for Health Research via the Collaboration for Leadership in Applied Health Research and Care - Nottinghamshire, Derbyshire and Lincolnshire (CLAHRC-NDL). More information about this programme can be found at: www.clarhc-ndl.nihr.ac.uk. The chief investigator and researcher are both based at the University of Nottingham.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has

been reviewed and given favourable opinion by Nottingham 1 Research Ethics Committee.

**Further information and contact details**

If you decide to take part in this study you will be given a copy of this information sheet and a copy of the consent form which you have signed. If you would like more information about this research project or have any questions or concerns, please contact:

**Researcher:** Hannah Jones Tel: 0115 823 1267 or email: Hannah.Jones@nottingham.ac.uk

If you are unable to get through to Hannah Jones, you can also contact our administrator Shirley Woolley on 0115 823 2472 or by email: Shirley.Wooley@nottingham.ac.uk

**Chief Investigator:** Professor Clive E Adams, Division of Psychiatry**,** University of Nottingham, University Park, Nottingham, NG7 2RD. Tel: 0115 82 31 274 email: clive.adams@nottingham.ac.uk

**Appendix 12. Service user consent form for OIDP**

**Service user consent form**

**Title of Study:** The three shires early intervention dental trial

**REC ref:**

Please initial box

**Name of Researchers**:

**Name of Participant:**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential, except where if during the interview I was to disclose anything which might cause risk to others or to the organisation, for example, bad practice. In those rare circumstances, essential information only would be disclosed to a third party, and this would be discussed with me first. ☐
4. I agree to complete the Quality of Life Questionnaire relating to my dental health. ☐
5. I agree to take part in the above study. ☐

Name of Participant Date Signature

Name of person taking consent Date Signature

**Appendix 13. Service user information sheet for dentist outcome**

**Service user information sheet**

**The three shires early intervention dental trial**

We would like to invite you to take part in a research study whose purpose is to improve the dental care of young people with mental health problems. To help you decide whether you wish to participate in the study, please take a moment to read this information sheet, to understand why the research is being done and how it could benefit service users. We also recommend that you talk to others about the study if you wish, or ask a member of the research team for more information.

**What is the purpose of the study?**

Oral health problems are not well recognized by mental health professionals and when treatment is accessed people with mental illnesses generally experience barriers to treatment. The purpose of this study is to improve the oral care of people with mental illness who are receiving treatment and care from Early Intervention teams in Derbyshire, Nottinghamshire & Lincolnshire. We wish to compare the effectiveness of two different approaches to improving the oral health of young people experiencing mental health problems.

**Why have I been invited?**

You have already participated in this study by completing, with the researcher, a questionnaire about the condition of your teeth and mouth in the past six months. We now want to ask a random selection (around 100 out of 600) of all the people who completed these questionnaires to provide us with more specific details regarding their dental health.

**Do I have to take part?**

Participation in this study is entirely voluntary. If you agree to take part, we will ask you to sign a consent form. If you change your mind, you are free to withdraw at any point, without giving a reason.

**What will I have to do if I participate?**

You will be contacted by a researcher who will arrange to meet you at a time and location convenient to you. You do not have to do anything, however, we will ask for your permission to contact your dentist and your care coordinator to provide us with any further details regarding your dental health. Should you agree to take part in this stage of the study, we will ask you to sign a consent form by the researcher (Hannah Jones), who will also be able to answer any questions that you may have.

**What exactly will happen during the study?**

Your team is already participating in the study, and you will have completed the oral impacts on daily performance questionnaire, we are now asking a random selection of participants to allow us to contact their dentist, see the description above.

**What are the possible benefits of taking part?**

Although we cannot guarantee the study will benefit all individual service users, however, we hope the information we get from this study will help improve the oral health of young people with mental health problems.

**Expenses and payments**

Participants will not be paid to participate in the trial. There should be no associated costs as a result of this trial. If travel expenses do occur as a result of participation they will be reimbursed.

**What are the possible disadvantages of taking part?**

Participating in this research should not cause you any inconvenience, discomfort or distress. Some of the questions we ask may be quite personal but any information you share will be kept strictly confidential and anonymous.

**What happens when the research study stops?**

You will receive ongoing support from your care coordinator.

**What if relevant new information becomes available?**

The Investigator will inform you of any relevant information that becomes available during the course of the study and will discuss with you whether you wish to continue with the study. If applicable you will be asked to sign revised consent forms.

**What will happen if I don't want to carry on with the study?**

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see contact details below). If you remain unhappy and with to complain formally, you can do this by contacting NHS complaints. Details can be obtained from your Trust.

**Will my participation in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Any information you share will be kept strictly confidential and anonymous. This means that the interview data will only be accessible to the research team and you will not be recognisable in research reports or publications. The only exception to this would be if during the interview you were to disclose anything which might cause risk to others or to the organisation, for example, bad practice. In those rare circumstances, we would disclose essential information only to a third party, and would ideally discuss with you first. All data collected will be anonymised and handled securely, according to the 1998 Data Protection Act and the University of Nottingham's own guidelines, and stored for seven years, before being destroyed safely.

**What will happen to the results of the research study?**

At the end of this study, a summary of our findings will be posted on the website of the Institute of Mental Health (www.institutemh.org.uk). We will also write papers for conferences and journal publications. We can also provide verbal and written feedback for service users in Early Intervention Teams in Nottinghamshire, Derbyshire & Lincolnshire.

**Who is organising and funding the research?**

This study is funded by the National Institute for Health Research via the Collaboration for Leadership in Applied Health Research and Care - Nottinghamshire, Derbyshire and Lincolnshire (CLAHRC-NDL). More information about this programme can be found at: www.clarhc-ndl.nihr.ac.uk. The chief investigator and researcher are both based at the University of Nottingham.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Nottingham 1 Research Ethics Committee.

**Further information and contact details**

If you decide to take part in this study you will be given a copy of this information sheet and a copy of the consent form which you have signed. If you would like more information about this research project or have any questions or concerns, please contact:

**Researcher:** Hannah Jones Tel: 0115 823 1267 or email:
Hannah.Jones@nottingham.ac.uk
If you are unable to get through to Hannah Jones, you can also contact our administrator Shirley Woolley on 0115 823 2472 or by email:
Shirley.Wooley@nottingham.ac.uk

**Chief Investigator:** Professor Clive E Adams, Division of Psychiatry**,** University of Nottingham, University Park, Nottingham, NG7 2RD. Tel: 0115 82 31 274 email: clive.adams@nottingham.ac.uk

**Appendix 14. Service user consent form for dentist outcome**

**Service user consent form**

**Title of Study:** The three shires early intervention dental trial

**REC ref:**

**Name of Researchers**:

**Name of Participant:**

**Please initial box**

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential, except where if during the interview I was to disclose anything which might cause risk to others or to the organisation, for example, bad practice. In those rare circumstances, essential information only would be disclosed to a third party, and this would be discussed with me first. ☐
4. I agree for data to be collected from my dentist and care co-ordinator, this will only be any oral health related information that I have generated. ☐
5. I agree to take part in the above study.

Name of Participant Date Signature

Name of person taking consent Date Signature

**Appendix 15. Sample letter to dentist**

Collaboration for Leadership in Applied Health Research and Care for
Nottinghamshire, Derbyshire and Lincolnshire (CLAHRC NDL)
Dental Trial
Institute of Mental Health
University of Nottingham Innovation Park
Triumph Road, Nottingham NG7 2TU
Tel: 0115 823 1267 Email: Hannah.Jones@Nottingham.ac.uk

Dear [dentist]

Request for information about dental treatment you have provided to your dental patient [name]

The purpose of this study is to improve the oral health of people with mental illness who are receiving treatment and care from Early Intervention in Psychosis teams in Derbyshire, Nottinghamshire & Lincolnshire. We wish to compare the effectiveness of two different approaches to improving the oral health of young people experiencing mental health problems. In this research there are two groups; in one group staff in early intervention in psychosis teams receive dental awareness training, complete a dental health checklist with their service users and distribute oral health packs to service users, while the other group receive care as usual. Your dental patient is participating in the trial and has given consent for us to contact you to ask for further information about their oral health.

We would be grateful if you would please read the enclosed information sheet and then if you are happy to take part and provide the requested information please sign the consent form.

Please return the completed Oral Health form and your signed consent form in the prepaid envelope to Hannah Jones at the University of Nottingham. If you have any questions or would like further information about any part of this study before deciding to take part contact Hannah Jones or Clive Adams:

Research Assistant: Hannah Jones
Tel: 0115 823 1267 or email: hannah.jones@nottingham.ac.uk
Chief Investigator: Professor Clive E Adams
Tel: 0115 82 31 287 email: clive.adams@nottingham.ac.uk

Yours sincerely

Hannah Jones

**Appendix 16. Dentist information sheet**

## Dentist information sheet

### What is the purpose of the study?

The purpose of this study is to improve the oral health of people with mental illness who are receiving treatment and care from Early Intervention in Psychosis teams in Derbyshire, Nottinghamshire & Lincolnshire. We wish to compare the effectiveness of two different approaches to improving the oral health of young people experiencing mental health problems. In this research there are two groups; in one group staff in early intervention in psychosis teams receive dental awareness training, complete a dental health checklist with their service users and distribute oral health packs to service users, while the other group receive care as usual.

### Why have I been contacted?

Your dental patient is participating in the trial and has given consent for us to contact you to ask for further information about their oral health.

### Do I have to take part?

Participation in this study is entirely voluntary. If you agree to take part, we will ask you to sign a consent form. If you change your mind, you are free to withdraw at any point, without giving a reason.

### What will I have to do if I participate?

You will be asked to complete a short one page form regarding the oral health of your dental patient. The form should take no more than 10 minutes to complete.

### What exactly will happen during the study?

You will be contacted with a request to complete the form at the 12 month follow-up period for the study. Data relating to any individual will not be published or reported in an identifiable manner.

**What are the possible benefits of taking part?**

Although we cannot guarantee the study will benefit all individual service users, however, we hope the information we get from this study will help improve the oral health of young people with mental health problems.

**Expenses and payments**

Participants will not be paid to participate in the trial. There should be no associated costs as a result of this trial. Pre-paid envelopes will be provided to return completed forms.

**What are the possible disadvantages of taking part?**

Participating in this research should not cause you any inconvenience, discomfort or distress.

**What happens when the research study stops?**

You will provide care as usual to your dental patient.

**What if relevant new information becomes available?**

The Investigator will inform you of any relevant information that becomes available during the course of the study and will discuss with you whether you wish to continue with the study. If applicable you will be asked to sign revised consent forms.

**What will happen if I don't want to carry on with the study?**

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions (researcher:

Hannah Jones tel: 0115 823 1267). If you remain unhappy and wish to complain formally you can do this by contacting NHS complaints, through the Patient Advice and Liaison Service (PALS) at your local hospitals trust (http://www.pals.nhs.uk/officemapsearch.aspx) or by contacting the Independent Complaints Advocacy Service (ICAS) for the East Midlands tel: 0808 802 3000.

**Will my participation in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Any information you share will be kept strictly confidential and anonymous and you will not be recognisable in research reports or publications. All data collected will be made anonymous and handled securely, according to the 1998 Data Protection Act and the University of Nottingham's own guidelines, and stored for seven years, before being destroyed safely.

**What will happen to the results of the research study?**

At the end of this study, a summary of our findings will be posted on the website of the Institute of Mental Health (www.institutemh.org.uk). We will also write papers for conferences and journal publications. We can also provide verbal and written feedback if requested.

**Who is organising and funding the research?**

This study is funded by the National Institute for Health Research via the Collaboration for Leadership in Applied Health Research and Care - Nottinghamshire, Derbyshire and Lincolnshire (CLAHRC-NDL). More information about this programme can be found at: www.clarhc-ndl.nihr.ac.uk. The chief investigator and researcher are both based at the University of Nottingham.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Nottingham 1 Research Ethics

Committee.

**Further information and contact details**

If you would like more information about this research project or have any questions or concerns, please contact:

**Research Assistant**: Hannah Jones

Tel: 0115 823 1267 or email: hannah.jones@nottingham.ac.uk

**Chief Investigator**: Professor Clive E Adams

Tel: 0115 82 31 287 email: clive.adams@nottingham.ac.uk

**Appendix 17. Dentist consent form**

## Dentist consent form

**Title of Study:** The three shires early intervention dental trial

**REC ref:** 11/EM/0205

**Name of Researchers**: Hannah Jones

**Please initial box**

**Name of Participant:**

1. I confirm that I have read and understand the information contained in the information sheet (dentist information sheet v2 December 2012) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I agree to complete the form regarding the oral health of my dental patient. ☐

5. I agree to take part in the above study.

| Name of Participant | Date | Signature |
|---|---|---|
| Name of person taking consent | Date | Signature |