MOUTHMATTERS

Full title: An intervention using mental health support workers as link workers to improve dental visiting in people with severe mental illness: The Mouth Matters in Mental Health Trial.

Short title: The Mouth Matters in Mental Health Study.

NHS Lancashire Care NHS Foundation Trust

MANCHESTER 1824 The University of Manchester

Lancaster University

UNIVERSITY OF LIVERPOOL

NHS Pennine Care NHS Foundation Trust

NHS Greater Manchester Mental Health NHS Foundation Trust

UNIVERSITY OF LEEDS

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles of GCP, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Study Sponsor:

Signature:
.....

Date:
...../...../.....
ddmmmyyyy

Name (please print):
.....

Position:
.....

Chief Investigator(s):

Signature: 

Date: 25.07.22
ddmmyyyy

Name: (please print):
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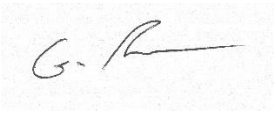
Signature: 

Date:
25.07.22
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Name: (please print): GIRVAN BURNSIDE

Position: LEAD STATISTICIAN

SIGNATURE PAGE

Site-leads

As site lead for the Mouth and Mind Study, I confirm that I will be responsible to ensure that all members of the local clinical trial team are appropriately trained on the trial protocol and have the relevant qualifications and experience to carry out their role in accordance with the trial protocol.

Name	Site	Signature	Date ddmmyyyy

Table of contents

1. Title

A randomised feasibility trial of an intervention using mental health support workers as link workers to improve dental visiting in people with severe mental illness: The Mouth and Mind Study.

2. Trial registration:

ISRCTN code: [ENTER]

ClinicalTrials.gov: [ENTER]

3. Protocol version

Version 4 (25.07.22)

4. Funding and sponsor reference

This project is funded by the National Institute for Health Research (NIHR) Health Services & Delivery Research (HS&DR) funding stream. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. Funding covers the period April 2022 to April 2024 (24 months). The design, management, analysis and reporting of the study are entirely independent of the funder. The project sponsor is Lancaster University.

5. Contributors to protocol

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6. Background and rationale

The term severe mental illness (SMI) denotes complex and enduring mental health difficulties (e.g. psychosis, bipolar disorder), which can be disabling and distressing to the individual. Oral health in people with SMI is much poorer than the general population [1]; people with SMI are over three times more likely to have total tooth loss, and have increased rates of decayed, missing or filled teeth [2,3]. In one study, a third of people with SMI reported that oral health had interfered with simple functions such as eating and drinking [4]. Poor oral health can also significantly affect individuals' self-esteem, quality of life and functioning [5,6] and increase social stigma [7]; all of which are barriers to recovery from SMI [8]. Poor oral health can limit employment opportunities [9], adding to the already substantial economic cost of these disorders [10]. Our PPI work suggests that oral health is a major concern for people with SMI. We need to develop evidence-based interventions to reduce oral health inequalities for this group.

There are many reasons why people with SMI have poor oral health. People with SMI are less likely to brush their teeth compared to the general population [11,12]. They are also are also more likely to smoke [13], use drugs [14], and experience poor diet [7], which can impact people's teeth and gums. Mental health treatments may also have an iatrogenic effect on oral health. Dry mouth is a side effect of psychotropic medication, and can increase oral health problems including dental decay (caries), oral candidiasis (fungal infection) and oral mucosal soreness, which can interfere with chewing and swallowing, affecting patients' nutritional status [15,16]. Hyposalivation increases with greater numbers of medications taken, meaning that the oral health of patients with the greatest mental health symptoms are the worst affected [17].

Dental services can prevent and treat oral health problems. However, patients with SMI often only attend their dentist at times of crisis, when more intrusive treatments (e.g. extractions) are needed [18]. One estimate suggests that only a third of patients with SMI attended an annual dental appointment over a three-year period [19]. Other studies report low utilization of dental services across regions and services [20,21]. Practical barriers, lack of motivation, perceived need, attitudes towards dental care, financial costs, and anxiety around visits may reduce the

likelihood of patients attending dental check-up appointments [22-25]. Helping patients with SMI to access dental services for routine preventive and therapeutic care is therefore an important first step in improving their oral health.

Existing interventions

In 2016, a Cochrane Review identified only three randomised controlled trials all of which were of educational oral health interventions among people with SMI. None of the studies provided useable data for the key outcomes of having seen a dentist in the past year, tooth brushing, chronic pain, clinically important adverse events, or emergency service use [26]. In preparation for this project, we completed a systematic search of oral health interventions completed since this review (i.e. 2016). We entered blocks of search terms into CINAHL, Medline and PsychInfo:

1. severe mental health OR severe mental illness OR serious mental health OR serious mental illness OR psychosis OR bipolar OR depression
2. oral health OR dental' OR teeth OR tooth OR dentist
3. Intervention OR link work OR trial OR RCT
4. 1 and 2 and 3

579 articles were screened at the title and abstract level, and four were screened at the full article level, yielding three relevant intervention evaluations on oral health in SMI. To summarise: i) The Three Shires Trial for oral health in Psychosis [27, 28] in the United Kingdom is the largest to date and evaluated a brief oral health checklist targeted at care coordinators for SMI patients. This related to dental service use and oral health behaviours and showed no significant impact on any outcome, including dental visiting, which reflects the wider literature showing that education alone has a limited impact on oral health outcomes [29]. ii) Kuo and colleagues [30] conducted a randomised trial in Taiwan evaluating an oral health promotion programme in 58 inpatients with SMI. The intervention consisted of education, demonstrations and a token economy for teeth cleaning for 12-weeks and demonstrated improvements in plaque and dental knowledge immediately after the intervention window. There was no focus on dental visiting. iii) de May and colleagues [31] completed a small pre-post test pilot (n = 24) of an education intervention around dental care for psychiatric nurses and outpatients with SMI in the Netherlands. They observed some improvements in dental knowledge and levels of plaque after four-weeks. Again, this study was in small numbers with a short-term follow-up and there was no assessment of dental visiting.

A search of NIHR, MRC, Wellcome and ISRCTN registered trials indicated only one current intervention evaluation focusing on oral health in SMI (ISRCTN10736304). This trial is non-randomised pre-post evaluation of the impact of free oral examination and dental treatment with an experienced dentist in people with SMI. It is funded by the Directorate of Health in Norway and does not focus on dental visiting. Our group are currently conducting the Mouth Matters Study (UKRI funded), but this project aims to explore the extent of poor oral health in SMI using epidemiological data. Initial analysis of the National Health and Nutrition Examination Survey 1999-2016 indicates that people with SMI are 40% more likely to experience tooth loss (unpublished). We are also conducting the i-Smile SMI project (UKRI funded) with the aim of developing an international network of collaborators (e.g. people with lived experience, dental and mental health experts) to overcome poor oral health outcomes in people with SMI. The planned outputs of this study include a consensus statement around how mental health and dental

services can better support patients around their oral health. We will therefore already have an extensive network of collaborators to support the dissemination of our findings. Both studies will complement the existing project.

Link work interventions

Link working offers an opportunity to overcome socio-economic and practical barriers to help-seeking that widen health inequalities around oral health [32], within a model of socially-engaged dentistry [33]. This form of social support may help to afford patients with the capacity, opportunity and motivation to visit the dentist. It may help to increase dental visiting in at risk populations. *Childsmile*, a national initiative in Scotland, found that vulnerable families receiving link-work were twice as likely to attend a dental practice [34]. Link work has been used to facilitate diabetes screening [35], appointments for people with tuberculosis [36], and fire safety assessments in at risk groups [37]. Benefits to chronic health conditions include improved health behaviours, resilience, illness management, and problem solving [38,39]. Link work has also effectively helped people with mental health difficulties to access services [40, 41] and better transition between primary and secondary care [42]. It has not yet been used to help people already in mental health services to access dental care.

Support workers within mental health services typically have no professional qualifications, but provide vital practical assistance to patients around their health. There are currently >25k support workers in core adult mental health services with plans to expand this workforce [43]. Key duties include building professional helping relationships, planning programmes of support, and signposting/referring patients to services [44]. Often support workers act as link workers supporting referrals and attendance at physical health appointments [45]. There is an opportunity to expand the remit of mental health support workers to oral health. This is logical given that: i) they already offer link work for other physical difficulties; ii) they are embedded in mental health services; and iii) link work has a burgeoning evidence base for promoting attendance at physical health appointments.

Why now?

Current approaches to increase regular health service usage among the population in general have led to the unintended consequence of increasing inequalities for disadvantaged groups. A systematic review showed that walk-in centres and NHS Direct advantage healthy middle class patients [46]. Reducing inequalities in dental visiting among vulnerable populations has recently been identified as an important national priority and one where relatively little previous research has been undertaken. NICE Public Health guidance [47] has pointed to the importance of community-based interventions for reducing oral health inequalities in high-risk adults. The James Lind national priority setting for oral health identified '*How can access to dental services be improved for people with additional needs*?' in its 10 top research priorities [48]. In the past year, the NIHR have listed improving access for vulnerable groups, reducing inequalities, and working with other health professionals in their top ten priorities for addressing oral health inequalities [49]. The World Health Organisation have also highlighted that action is needed to tackle oral health inequalities that disproportionally affect the most socially-disadvantaged members of society [50].

The COVID-19 pandemic will likely worsen existing health inequalities, including those in oral health [51]. Anxiety about the virus, competing priorities, and backlog in accessing dental services, may be additional barriers for people with SMI. Furthermore, there is data that risk factors for poor oral health, including increased snacking, have elevated over the past year [52]. Delayed help seeking may have increased treatment needs and reduce future likelihood of preventative and restorative dental work following the pandemic. People with SMI may be particularly disadvantaged in seeking help following the pandemic [53]. Thus, more than ever, this research is needed to overcome barriers to dental visiting in people with SMI.

The project takes place across three sites (Lancashire & South Cumbria NHS Foundation Trust, LSCFT; Pennine Care NHS Foundation Trust, PCFT; and Greater Manchester Mental Health Foundation Trust, GMMH) in the North West of England. A recent review of geographical oral health disparities [54] has indicated geographical variation in oral health, with the North of England experiencing much worse outcomes, partly explained by differences in deprivation. The authors note that 'children in Blackburn are four times more likely to have missing, decayed, or filled teeth than children in South Gloucestershire' (*p*.3). Again, these inequalities are likely to be exacerbated by the recent pandemic. Interventions that are feasible and effective in the most deprived areas of the UK where dental outcomes are poor are greatly needed to address such inequalities.

Support workers are core members of multi-disciplinary teams and are part of the expansion of the NHS workforce. These workers focus on providing personalised care that takes a whole-system approach, integrating services around the person, and therefore the link work role is consistent with their job description. Upskilling mental health support workers who are typically NHS Band 4 offers a cost efficient way to deliver this intervention. Our PPI work has indicated that support workers are well-placed and motivated to offer support around oral health. This available resource is therefore a valuable and timely opportunity.

7. Aims of research

The aim is to investigate the feasibility and acceptability of a link work intervention using support workers to increase planned dental care visits for patients with SMI, and through this to improve their oral health (MRC Complex Intervention Cycle Stage 2).

1. To understand what constitutes best practice when delivering link work around dental visiting.
2. To identify what training needs exist for support workers around link work.
3. To determine whether patients with SMI are willing to be randomised to a trial targeting dental visiting.
4. To understand whether it is feasible to collect clinical outcome and planned dental appointment data in this population.
5. To explore if, and how, patients with SMI engage with a link work intervention.
6. To understand the potential factors impacting (e.g. facilitators and barriers) acceptability and delivery.

Key outputs

1. A best practice manual to aid the link work intervention that is structured; easy to understand and implement; accounts for different service configurations; user-friendly for support workers; and helpful and acceptable to people with SMI.
2. Data on the acceptability and feasibility of assessing clinical and dental visiting outcomes.
3. Information on rates of recruitment, willingness to consent, adherence to treatment, attrition, missing data, and safety.
4. Data on outcomes and retention rates on which to base a sample size calculation for a definitive trial.
5. Qualitative data to configure and optimise the intervention and trial design.

8. Trial design

We will conduct a randomised controlled feasibility trial with two groups. Participants will be randomised at a ratio of 1:1 to either: Treatment as usual (TAU) or TAU plus the link work intervention. Both arms will also receive any concomitant interventions deemed necessary as part of their routine care. Research assistants (RAs) and a dental therapist will assess clinical outcomes, including self-report and objective oral health outcomes, self-esteem, self-efficacy, and depression at baseline and after nine months. Embedded qualitative work will explore trial and intervention processes.

9. Study settings

We will recruit participants from secondary care mental health services, namely Community Mental Health Team (CMHT) and Early Intervention Services (EIS). CMHT work with complex mental health difficulties in the community, including psychosis, bipolar disorder, major depression, personality disorders, and anxiety disorders. They are the main form of community support for SMI in the NHS and present in every locality. EIS support people with first episode psychosis for up to three years. They are community-based, multidisciplinary teams providing intensive support in order to improve mental health outcomes. Both services comprise psychiatrists, psychologists, psychiatric nurses, social workers, occupational therapists, and support workers. The inclusion of multiple trusts will help to establish the feasibility of the trial and intervention across different geographical areas, and service and organisational configurations. In terms of patient numbers, in LSCFT there are currently >9000 people registered across 12 CMHT and three EIS. In GMMH there are approximately 13404 patients registered across 12 CMHT and four EIS. In PCFT, there are approximately 5900 patients registered across five CMHT and four EIS. Therefore, we will recruit from a large population increasing our chances of success.

10. Eligibility criteria

We have set the inclusion criteria to be as inclusive and pragmatic as possible. The intervention should be available to most service users accessing secondary care mental health services who have not been to the dentist in the past three years. The choice of three years without treatment or a check-up is based on NICE recall guidance, which recommends that patients have recall or

check-up periods tailored to their risk of poor oral health, up to a maximum of two years for people with low risk. The pandemic will have further lengthened recall periods because of a period of closure of dental practices and the backlog created. Those who have not attended for three years are unlikely to be accessing a dentist. Exclusions are based on the need to keep research participants and others safe. We have costed interpreter and translator time to accommodate different cultural backgrounds. We will try to enable and support people from different backgrounds and cultures to take part.

Inclusion criteria:

- Aged >18.
- Able to provide informed consent
- Receipt of care from a CMHT and EIS at the point of referral.
- No routine and planned dental appointment in the past three years. The person should not have accessed a dental service (e.g. high street dentist, special care dentist service) for routine or planned dental care in the past three years. This would include any dental examination, diagnosis, advice or treatment (e.g. fillings, root canal, extractions, crowns, dentures, bridges) resulting from a routine (non-emergency) appointment at a dental service. We do not consider emergency dental care (e.g. attendance at A&E, dental hospital) within this definition, although any follow-up routine and planned appointments with a dentist would exclude the person from taking part.

Exclusion criteria:

- Inpatient status on a psychiatric or secure ward. We will allow participants in supported living to take part as long as they are in receipt of care from a CMHT/EIS.
- Immediate risk to self or others operationalised as the presence of active intent or planning to harm oneself or others in the near future (e.g. next month). Where individuals are excluded on this basis, with the person's consent, the researcher will aim to re-contact them and the referrer in approximately one-month's time (or a time period agreed in collaboration with the individual) to determine if risk has subsided to a point where they are now eligible.
- Enrolled in a dental trial.

11. Intervention

Design and theoretical framework:

The research follows an 'inclusion oral health' framework [55] which is defined as: *'A theoretically engaged understanding of how social exclusion is produced and experienced, and how forms of exclusion and discrimination intersect to compound health outcomes. Inclusion oral health focuses on developing innovative inter-sectoral solutions to tackle the inequities of people enduring extreme oral health' (p.4).* This approach recognises that oral health inequalities result from social exclusion, wider structural disadvantage, and barriers within the dental health care system. For example, a patient with SMI may experience social exclusion through negative associations with mental health conditions that leads them to withdraw from health services that may perpetuate the stigma, worsening their health. Intersectionality forms of disadvantage are also important to consider within this framework. Importantly, disadvantage through mental

health can intersect with other forms of disadvantage, such as racism, sexism, classism, and ableism [56].

The intervention strives to build motivation to change dental visiting behaviour in people with SMI through mental health support workers acting as link workers as well as their confidence in being able to enact the behaviour. The intervention also aims to open more opportunity to enact regular dental visiting behaviour through a support worker advocacy for the patients, whilst helping them to navigate the dental system and forge a pathway to care. It is consistent with the COM-B model [57], which suggests that capability, opportunity, and motivation interact to facilitate behaviour change. This model acknowledges that intra-and external factors may limit behaviour, which is particularly true of dental visiting. It suggests that the environment and its cultural milieu may affect opportunity; here, routine mental health care may not consider or prompt consideration of oral health and therefore opportunities for behaviour change are lost. The current intervention builds psychological and physical capacity around dental visiting (capability), including self-efficacy around attending dental appointments [58]. It also addresses factors outside the individual that might act as barriers (opportunity), and energises and enthuses people to act by reinforcing perceived benefits of engaging (motivation).

Outline of intervention

The mental health link work intervention uses support workers to empower and assist people with SMI currently supported by secondary care mental health services, but not dental services, to access planned dental appointments. The link work intervention in the study proposal has the following dimensions:

- Delivered by Band 4 mental health support workers
- Focused on oral health as the health issue
- Setting is in secondary mental health care linking to dental care
- Primary role is navigating or bridging services.
- It builds motivation where needed and offers advocacy.
- Its builds self-efficacy through social persuasion, positive reinforcement and positive experiences of dental visits and interacting with dental services
- Training is given to support intervention delivery
- This is a non-volunteer model
- They are linked to health services and work autonomously
- Accountability is to professionals rather than the community

We are looking at improving access for patients with SMI through a responsive and inclusive model of delivery using link support workers. Support workers use a personalised care model that prioritises patient needs and goals. We will also utilise lived experience and PPI within the development of the model to ensure that our approach is inclusive.

The link worker will act as an advocate addressing environmental barriers to dental visiting, affording *opportunity* by supporting the individual to register at a dentist; book appointments; access special care dentistry (if needed); plan appointments; attend appointments through joint visiting/problem solving; apply for free/subsidised dental care; and advocate on behalf of patients. In order to build psychological *capability*, the link worker will promote self-efficacy around dental visiting through *demystification, knowledge exchange, reassurance, positive reinforcements, and empathic social support.* Where possible, link workers will enable and

upskill patients to take action themselves so that learning may be taken forward and generalised to others situations in the future. At times, patients may lack *motivation* or fail to see the rationale for attending the dentist. Support workers will then use simple motivational strategies, based on a motivational interviewing questioning style, to reinforce reasons for engaging [59].

Support workers will collaboratively enable people to make meaningful behaviour changes consistent with their priorities and needs. We will monitor and report fidelity through sessional checklists. The intervention includes ≤6 1:1 sessions within nine months. Support workers may also assist people face-to-face or remotely by phone, telemedicine platforms (e.g. Teams, Zoom), letter, email, or via staff/carers. Visits will occur at places of mutual convenience (e.g. homes, GPs). Staff may accompany patients to dental appointments. Our definition of support worker is broad and includes recovery and peer workers, and assistant practitioners. Staff will receive training (partly determined by ongoing PPI work) in behaviour change methods, benefit applications, and dental health provision. The support worker will share information with patients about local services, what to expect at dental visits, and available financial support. They will regularly review and monitor which NHS dentists are accepting patients in order to offer timely and relevant recommendations and support.

TAU

TAU for people with SMI typically involves meeting with a care coordinator, support worker, psychologist, occupational therapist, and/or psychiatrist for care around mental health. TAU also includes medication and case management. Services sometimes offer support around physical health issues, but rarely oral health. Patients may access assessment, information, or treatment from dental services as normal. The study will illuminate what constitutes TAU in regards to oral health for people with SMI. We will not withhold, but rather monitor assessment and treatment for oral health in the TAU arm.

12. Outcomes

Feasibility outcomes

We will record information on participant flow, including the numbers of referrals, consents, and withdrawals. Success criteria are as follows:

(i) **Recruitment rates**: Data on ability to randomise 84 participants to target in a 7-month recruitment window. Green ≥80%. Amber 60-79%. Red ≤59%.

(ii) **Visiting data:** Percentage of participants with available data on dental visiting via self-report or BSA. Green ≥90%. Amber 60-89%. Red ≤59%.

(iii) **Clinical exam:** Percentage of participants completing the dental examination. Green ≥80%. Amber 60-79%. Red: ≤59%.

(iv) **Adherence to intervention:** Percentage of participants receiving intervention ≥1 sessions during nine month window. Green ≥80%. Amber 60-79%. Red ≤59%.

(v) **Intervention and trial protocol:** Qualitative data to understand the acceptability and feasibility of the procedures, assessments, and intervention to inform a full trial and service delivery.

(vi) **Safety of intervention:** Monitoring and review of research related serious adverse events (SAEs). The TSC will oversee SAEs across treatment arms. We will discontinue the trial if the intervention or procedures elevate risk.

All green outcomes: no/minor revisions prior to a definitive trial. ≥1 amber outcomes: substantial alterations to the trial protocol, assessments, or intervention, which will be supported by the qualitative work stream and discussed with the trial management team and TSC. ≥1 red outcomes: trial is unlikely to progress at that site or that very substantial amendments are needed. Should we demonstrate feasibility, we will immediately submit for publication and apply for NIHR funding to conduct a definitive trial.

Proposed primary outcomes for definitive trial:

Assessments will take place at baseline (prior to intervention) and after nine months (following the intervention). This window will allow enough time for a planned care appointment to have taken place and a treatment course started and submitted to the NHS Business Services Authority (BSA) from which we will gather this data alongside self-report.

A research assistant will conduct the assessments, with support from a dental therapist who will complete the dental examination. The primary outcome is **planned care appointments** with a dental service, measured through self-report and BSA. NHS England collects information on visiting behaviour via the BSA with inaccuracies <1% [60]. Our PPI work identified dental visiting as an important target for intervention. We will assess feasibility of recording BSA data in this context. RH and GB have used the BSA for scientific purposes. Data will be matched using surname, first initial, data of birth and gender before being anonymised and entered into a data master file. The BSA will be used to collect data on whether a planned care appointment has taken place, what level of treatment occurred, and whether the participant paid for the appointment or had access to free dental care. We anticipate that the use of BSA data could overcome problems around attrition and provide an objective measure of dental visiting, treatment and access to free dental care. A downside of BSA data is that it only provides data for attendance at an NHS (not private) practice.

We will collect self-report data on dental visiting asking people to confirm the date of appointment and dental surgery. We will select one of these measures as the primary outcome for a definitive trial based on retention in the feasibility study; levels of missing data for self-report items compared to routinely held (NHS BSA) data, the qualitative findings, and ongoing PPI work.

Self-report assessments

We have summarised the assessment battery in Table 1. Dental therapists will complete a brief dental examination in community settings to assess clinical outcomes, including the number of decayed, missed, and filled teeth and visible pulpal involvement, ulceration due to trauma, fistula, and abscess. They will also record the presence/absence of gum hyperplasia.
We will assess the following self-report outcomes:

- Orofacial pain using the gold-standard Brief Pain Inventory – short form [61].
- Pain related disability using the Manchester Orofacial Pain Disability Scale [62]
- Oral health related quality of life using the Oral Health Impact Profile [63].
- Self-efficacy around dental visiting will be measured using an item adapted from Armitage et al 64]: *'How confident are you that you will be able to attend a dental appointment?'* (1, no confident; 7, very confident).

- Self-esteem using the Rosenberg Self-esteem Scale (RSES; [65])
- Dental anxiety using the Modified Dental Anxiety Scale [66]
- Depression using the Patient Health Questionnaire [67]
- Quality adjusted life year using the EuroQol 5 Dimension (EQ-5D-5L [68])

At baseline, we will assess bruxism using items from Aggarwal et al [69]: *'Do you grind you teeth during the day or at night?'* Yes/No. *'Has someone told you that you grind your teeth?'* Yes/No and hyposalivation through the item 'Does your mouth usually feel dry?' Yes/No [X] for descriptive purposes. The Mini International Neuropsychiatric Interview [71](excluding suicidal behaviour, antisocial personality disorder or eating disorder subscales) will be included as a baseline measure to assess mental health diagnosis and understand the diagnostic composition of the sample.

Demographic and clinical information will include ethnicity, diagnosis, medication, illness length, inpatient admissions, service, cigarette/substance/alcohol use (items from [72]). We will assess attendance at urgent dental services, GP, A&E, or mental health wards, and prescription of antibiotics or painkillers. To assess the feasibility of assessing clinical information as secondary outcomes for a main trail, we will also collect data on whether the person has access to free dental care, is currently on a dentist list, the number of routine dental visits, and data on self-management, namely use of *brushing, flossing, and mouthwash.* We will record data on the number and length of intervention related activity (e.g. delivery, clinical note keeping, clinical supervision) to calculate estimates of the costs of the intervention.

Table 1. Summary of assessment time points.

Assessment	**Baseline**	**Nine month follow-up**
Demographic information	✓	
Background clinical information	✓	
Updated clinical information		✓
Self-report dental visiting	✓	✓
BSA recorded dental visiting	✓	✓
Decayed, missing, or filled teeth (DMFT): Dental examination	✓	✓
Pulpal involvement, ulceration due to trauma, fistula, and abscess (PUFA): Dental examination	✓	✓
Modified Plaque Score: Dental examination	✓	✓
Brief Pain Inventory (BPI)	✓	✓
Manchester Orofacial Pain Disability Scale (MOPDS)	✓	✓
Oral Health Impact Profile (OHIP)	✓	✓
Self-report bruxism / dry mouth	✓	
Self-efficacy item	✓	✓
Rosenberg Self-Esteem Scale (RSES)	✓	✓
Modified Dental Anxiety Scale	✓	✓
Patient Health Questionnaire -9	✓	✓

EQ-5D-5	✓	✓
Mini International Neuropsychiatric Interview	✓	

RAs will recruit participants, deliver self-report assessments, arrange appointments, complete paperwork and data entry, write field notes, and facilitate data extraction from notes. They will send out reminders and thank you messages to participants every three months to increase engagement with the trial protocols and reduce attrition.

We will record the number of serious adverse events and number of participants with at least one serious adverse event, and report these for the two study arms. We define a serious adverse event as any untoward medical occurrence that: results in death; is life threatening; requires inpatient hospitalisation or prolongation of existing hospitalisation; or results in persistent or significant disability/incapacity. Other important medical events may also be considered serious if they jeopardize the participant or require an intervention to prevent one of the above consequences. We will also measure adverse reactions and serious adverse reactions. The latter are adverse events that are both serious and, in the opinion of the reporting investigator, believed with reasonable probability to be due to the link work intervention, assessments, or qualitative interview, based on the information provided.

We will reimburse participants £20 for each of the assessments (baseline and nine-months) plus additional costs incurred for travel. This is based on INVOLVE guidance, PPI feedback, and is consistent with our past trials. Participants will be recognised and thanked for taking part in letters sent during the project and the dissemination materials, whilst maintaining confidentiality. There will be no payments for engaging with the intervention sessions.

Dental examination

The dental therapist will gather dental examination data using portable equipment. They will be accompanied by a research assistant who will collect baselines measures and assist the therapist during the examination. The assessment battery is kept relatively brief to minimise burden on participants and to allow for improved access to the study. We will permit participants who decline the dental examination to be randomised into the trial in order to not exclude key groups of participants and to minimise the chances of study bias. We will monitor willingness to complete the assessments as a feasibility outcome. The brief dental examination will assess the number of decayed, missed, and filled teeth and visible pulpal involvement, ulceration due to trauma, fistula, and abscess.

Clinical examination equipment set-up and seating of participant

The participant will be seated in a comfortable chair with good head support, and to which the dental therapist can get access such as in a chair with head support in the living room. An LED head lamp will be used instead of a fixed lamp to avoid the problems of positioning of the lamp, the availability of power points, and the risk of the clamp or base damaging surfaces. The clinical examination is not so exacting that a standard head torch is required but the same make/model should be used throughout the survey.

Preparation for the examination

The instruments will be laid out on a clean tissue on a hard surface out of sight of the participant if possible but allowing easy access. The light will be set up and adjusted and dark protective glasses placed on the subject. To ensure good lighting the dental therapist Distractions or extraneous noise will be tactfully removed to allow the dental therapist calls to be heard by the research assistant who will record scores on the data collection sheet (see CRF). For example pets will be shut out and the television sound turned off or down. The examination will only proceed once the participant is comfortably positioned and the oral cavity can be viewed by the dental therapist. The participant will be fully informed about the examination and have had the opportunity to ask questions.

Infection control

The dental therapist will carry sufficient sets of sterile instruments to ensure that there are sterile instruments for every examination. Following the examination these will be placed in a sealed container for transport back to the clinical base where the instruments will be sterilized according to local procedures. The dental therapist will wear a clean pair of latex free gloves for the examination of each participant. These will be disposed of into a standard clinical waste bag with any tissues and wipes after the exam. This will be disposed of on return to the clinic along with normal clinical waste.

Measurements

DMFT score

An examination for dental caries in permanent teeth will involve examining 32 teeth (i.e. all permanent teeth including wisdom teeth) with a metallic periodontal probe (Community Periodontal Index (CPI) probe) and a plane mouth mirror. The permanent dentition status of each tooth (crown and root) will be recorded as a score from the above chart as follows:

- 0: Sound - A crown/root is coded as sound if it shows no evidence of treated or untreated clinical caries. The stages of caries that precede cavitation, as well as other conditions similar to the early stages of caries, are excluded because they cannot be reliably identified in most field conditions in which epidemiological surveys are conducted.
- 1 = Natural tooth present with arrested caries
- 2 = Natural tooth present with caries into dentine
- 3 = Natural tooth present with caries into the pulp/retained roots
- 4 = Natural tooth present with filling(s) and caries
- 5 = Natural tooth present with filling(s)
- R = Natural tooth present with filling(s) need replacing
- 6 = Natural tooth missing, any reason, with no replacement
- C = Natural tooth with a crown
- F = Natural tooth replaced by bridge pontic, implant pontic or implant
- D = Natural tooth replaced by denture tooth

Individual DMFT value is the sum of the number of D (Decayed), M (Missing) due to caries, and F (Filled) teeth in the permanent teeth. The D component includes all teeth with codes 1, 2 or 3. The M component comprises teeth coded 6. The F component includes only teeth with code 4,5 or R. Teeth coded F or C (fixed dental prosthesis/bridge abutment, special crown or veneer/implant) are not included in calculations of DMFT.

PUFA score:
This will be recorded to examine the clinical consequences of untreated dental caries which previous literature has shown is high in people with SMI. We will record PUFA score in accordance with the criteria set out by Monse et al (73) Scoring and recording will be as follows:

- P: Pulpal involvement is recorded when the opening of the pulp chamber is visible or when the coronal tooth structures have been destroyed by the carious process and only roots or root fragments are left. No probing is performed to diagnose pulpal involvement.
- U: Ulceration due to trauma from sharp pieces of tooth is recorded when sharp edges of a dislocated tooth with pulpal involvement or root fragments have caused traumatic ulceration of the surrounding soft tissues, e.g., tongue or buccal mucosa.
- F: Fistula is scored when a pus releasing sinus tract related to a tooth with pulpal involvement is present.
- A: Abscess is scored when a pus containing swelling related to a tooth with pulpal involvement is present.

The PUFA score per person is calculated in the same cumulative way as for the DMFT and represents the number of teeth that meet the PUFA diagnostic criteria. Thus, for an adult in our study the score can range from 0 to 32 PUFA.

The Modified Plaque Score (MPS; adapted from gums do matter guidelines; 74)

A coding system has been developed based on the Silness and Löe index (75) using Ramfjord's teeth. The locally derived system involves assessing six teeth representative of the entire dentition, for the worst plaque score on each tooth surface from visual examination and, where necessary, the use of a probe to detect the presence of plaque. These six teeth are the UL4 UL1 UR6 LL6 LR1 LR4.

Each surface; Interproximal, buccal and lingual or palatal of the six teeth should be viewed in turn and the highest level of visible plaque on each surface should be scored '2'. For each surface where no plaque is visible, a probe should be used to skim along each surface near the gingival margin and, if this reveals plaque as present, that surface should be scored as code '1'. Where use of a probe reveals no plaque on the respective surface of the tooth then that surface should score '0'. Each surface is scored individually and then the total added together. This is then divided by 36 and multiplied by 100 to calculate the percentage plaque score. If one of the Ramfjord's teeth is absent, then a similar representative tooth should be examined instead. Therefore, a central incisor can be substituted for the lateral incisor or the alterative central incisor. Likewise a second premolar can be substituted for a first premolar when absent and similarly a second molar can be substituted for a first molar when absent. If for some reason examination cannot be undertaken due to the inability to substitute an appropriate representative tooth, then Code N should be assigned. The total plaque score is then divided by a value of 6 less for each tooth missing. So for example, if N is scored then the total plaque score of the surfaces added together would be divided by 30 instead of 36.

The scores codes are:
0 - No plaque visible, even when a probe is used
1 - Some plaque visible only when a probe was used to skim the tooth surface
2 - Visible amount of plaque which can be seen without use of a probe
N - No measurement could be made for this surface/tooth

Reporting of serious soft tissue pathology
If the examining dental therapist notices a lesion when undertaking the PUFA scoring, which he /she considers may be serious and potentially life threatening (such as a suspected malignancy, this will be noted as needing further investigation). Please see the risk protocol for reporting of serious soft tissue pathology and guidance that will be followed. Please note that examiners are unlikely to encounter serious pathology, as the incidence of legions is very low. However, given their seriousness, risk protocols will be followed, including sharing information with participants and, with consent, their GP.

BSA data

The BSA application will collect data on routine dental visiting. We will also collect data on any appointments, treatments or procedures that have taken place, access to exceptions (free dental care), and distance travelled to an appointment. At this stage, we are interested in the feasibility of accessing this data through the BSA. However, this would important clinical outcome data for a full trial.

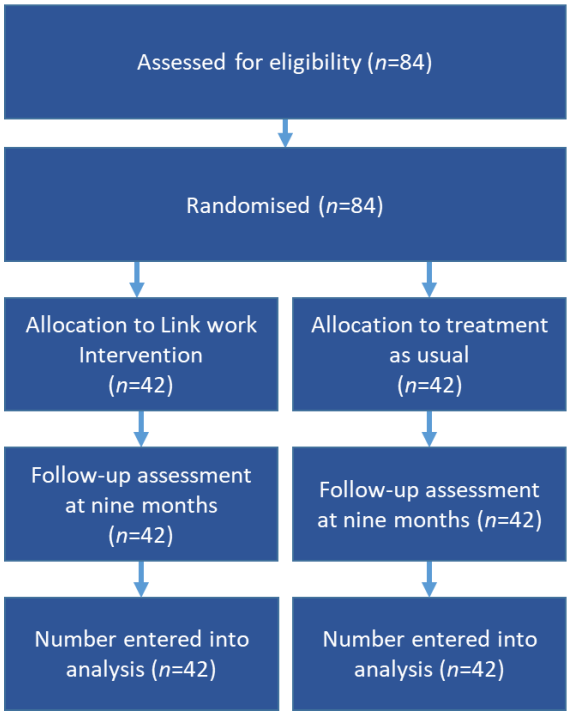
Table 2. Variables collected during BSA application
Treatment Acceptance Date Treatment Completion Date All Patient Charge Bands Urgent/Occasional Band 1, Band 2, Band 3 Continuation of Treatment Y/N (Y= further treatment needed within 2 months) General Free Repair/Replacement ***** Failed To Return / Incomplete (Band of Actual Treatment) • Failed To Return / Incomplete: Patient Charge Band associated with an incomplete course of treatment as stated in Part 3 of the FP1 Scale And Polish (Yes/No) * Fluoride Varnish* • Count of FP17s which included a fluoride varnish treatment (Y/N) Fissure Sealants* • Count of FP17s which included fissure sealants (Y/N) Radiograph* Endodontic Treatment* Permanent Fillings* Extractions* Crowns Provided Upper Denture Acrylic* Lower Denture Acrylic* Upper Denture Metal*

Lower Denture Metal*
Veneers Applied*
Inlays*
Bridges Fitted
Referral For Advanced Mandatory Services
Examination
Antibiotic Items Prescribed*
Other Treatment*
Domiciliary Visits
Sedation
Exemption Status (Exemption status as per part 4 of the FP17)
Distance Travelled

13. Participant timeline

We will randomise 84 participants (42 per arm; 28 per site) recruited from adult CMHTs and EIS. With a recruitment rate of four participants per site, this will achieve recruitment targets in seven months. A TSC will advise on and troubleshoot all aspects of the work (e.g. recruitment, retention, safety monitoring). The research clinicians will contact participants between assessments to offer reminders and gather updated contact information to increase retention. We will record the frequency and lengths of all research and clinical contacts.

Fig 1. Flow chart



14. Sample size

The target sample size is 84 participants (42 per group) with a recruitment rate of four participants per month for seven months at each of the three sites. The sample size has been calculated to ensure that for our feasibility proportions (from criteria i) to iii)), if we observe a proportion of 70% or more, that the lower end of the 95% confidence interval will be above the 60% amber/red cut-off. 28 per site will enable learning across locations and service provisions, increasing generalisability of the findings. We have an excellent record of recruiting and retaining patients with SMI from a variety of backgrounds in clinical trials [e.g. 76, 77].

15. Recruitment

We will recruit from secondary care services (EIS, CMHT) in three participating NHS Trusts, namely LSCFT, GMMH, and PCFT. Our definition of CMHTs includes community care hubs and any other new terms for community secondary care mental health services. It also includes any specialist service working into the CMHT (e.g. hub and spoke model psychological therapy teams, occupational therapy services). The research team have excellent working collaborations with these organisations with most holding joint appointments. Each site will have a designated research assistant (RA1-3) who will facilitate recruitment. Typically, this will involve meeting with clinical services (e.g. attending team meetings) to inform them about the study and share recruitment materials (e.g. information packs). Clinical staff will then disseminate the research to

participants who can opt into taking part with support from clinical studies officers (CSOs)/Assistant Clinical Research Practitioners (ACRPs) and the study research assistants.

. Participants will also be able to self-refer to the project upon seeing advertisements. Potential participants will have a brief screening telephone, video call, or face-to-face visit (according to preference) where the RA answer questions, ensure that they meet the inclusion/exclusion criteria, and that they have read and understood a PIS. If not, the PIS can be sent out in the post or via email allowing time for them to read and reflect on the information. After >24 hours to consider the information, the RA will meet with the participant at a place of mutual convenience (e.g. home, GP, Trust location) to complete the written consent process and administer the baseline assessments. The dental therapist will join for part of this assessment to complete the dental examination. If the participant does not wish to complete the dental examination, then they will still be permitted to be entered into the trial. We will permit self-report assessments to be completed remotely via telephone/video calls. This process is based on the recruitment methods in previous trials, shaped by PPI feedback, which we have found to be inclusive and fair. We will allow the option of audio recorded consent whereby the person states their agreement to the statements on the consent form and their name and date.

16. Sequence generation, allocation concealment, and implementation.

Randomisation will be via a secure 24-hour web-based randomisation programme managed centrally by Liverpool Clinical Trials Centre (LCTC). Allocation sequences will be computer generated and concealed from staff recruiting participants to the trial using the secure internet-based system. A personal login username and password, provided by LCTC, will be required to access the randomisation system; designated research staff will be issued with their personal login and password upon completion of training in the use of the system. When the system requirements (consent and eligibility) are confirmed the participant allocation and a unique trial number (randomisation number) will be displayed on a secure webpage and an automated email confirmation will be sent to designated personnel and to the trial co-ordinator. Participants will be allocated to one of the two groups, with a 1:1 ratio, stratified by site (LSCFT, PCFT, GMMH).

17. Blinding

Researchers undertaking the clinical assessments will be blind to the treatment allocation. We will monitor and record all breaking of the blind on a structured form. The senior management team and TSC will review blind breaks to establish and implement learning and reduce further blind breaks. Where possible, when one researcher becomes unblinded, a second unblinded researcher will complete the assessment. Deliberate un-blinding of the researchers during the trial is unlikely, but will be considered by the senior management team and could occur in cases of risk or safeguarding.

18. Data collection methods

Research staff and a dental therapist will collect data at baseline and after nine months. This will be in the form of questionnaires and interviews (see assessments). Self-report assessments and the dental examination will be employed face-to-face. Should face-to-face contact be difficult, we will allow for remote assessment (e.g. telephone, web platform) for the self-report measures (in such instances, dental exam data will be completed separately or treated as missing). We will provide training to research staff in standardised approaches to data collections. We will train staff in the MINI diagnostic interview and record a subset of interviews, which will be rated by a second researcher to ensure good interview technique, standardised questioning, and reliability of scoring.

Participant retention will be supported by regular telephone "check-ins" with participants involved in the trial. We will arrange these between follow-up assessment time-point to remind the participant of upcoming assessments and to give them the opportunity to ask questions. We will disseminate a study newsletter to current participants providing general information on the progress of the study and related news.

19. Data management

The main trial database will be held at LCTC. The database will be developed in REDCap. A separate data management plan will be developed which will provide detail regarding the internal processes that will be conducted at LCTC throughout the trial. Data will be entered directly into the REDCap database at site by staff members trained in data entry by the trial team. The sites will enter/transfer all study data at the earliest possible opportunity. All study data will be stored separately to personal identifiable data and the only way of linking these will be via a Participant Identification Number (PIN) held by the research team. Personal data will not be shared outside of the study team except for auditing purposes and the BSA application. Paper consent forms will be stored in a locked filing cabinet, within a locked office on NHS premises. Consent recordings will be stored on a secure NHS shared drives accessible only to members of the research team.

Written interview transcripts (saved in .docx format) and audio recordings (saved in .wav or .mp3 file formats) will be shared for qualitative data analysis using encrypted devices (e.g. Dictaphones) or secure file transfer. All audio recordings will be destroyed following transcription. Transcripts will have all personal or identifiable information removed.

Anonymised copies of the full dataset will be made available upon requested as per NIHR good practice guidelines. Hard copies of anonymised data will be held for a minimum of 5 years after completion of the study. All personal data would be destroyed upon completion of the study, with the exception of consent forms (or consent recordings), which need to be held for five years, and interview audio files, which will be deleted after transcription. Anonymised datasets may be made available for research purposes after the completion of the project to support further work in this area. Additional detail is available in the study Data Management Plan. At the end of the retention period, paper will be destroyed using paper shredders. Electronic data will be deleted.

BSA application

Some personal data will need to be shared with the Business Services Authority (first initial, surname, date of birth, gender and postcode) for the purpose of extracting data on dental attendance for each participant. LCTC will be in charge of submitting the BSA application and linking the extracted data to the master data file (research data), with support from the co-applicants (VA, JPC). NHS sites will provide LCTC with this personal data via a secure file transfer. LCTC will then submit the combined persona data from across NHS Trusts to the BSA who will extract and transfer the data on dental visiting to the LCTC. LCTC will then link this data to the research master data file.

The BSA will not have access to any research data. They will be required to keep any data secure and confidential. Personal data will be transferred securely between LCTC, NHS Trusts and the BSA. The BSA and LCTC will delete the personal data once information on dental attendance has been extracted and linked to the master datafile. We will gather informed consent from participants to use their data in this way (see consent form and PIS).

20. Statistical analysis

A full detailed statistical analysis plan will be developed prior to the analysis of the trial, following the standard operating procedures from LCTC. We will analyse data at the end of the last follow-up assessment, reporting outcomes in line with the updated CONSORT 2010 Statement for randomised pilot and feasibility trials, summarising recruitment and attrition rates, willingness to be randomised, and loss to follow-up. Analyses of intervention efficacy will not be investigated, but outcome data will be summarised to inform a definitive trial (e.g. mean, *SD* of outcomes).

The statistical analysis for this feasibility study will summarise the quantities specified in the feasibility criteria (recruitment rates, available BSA data, completed dental examinations, interventions received). These will be presented as percentages, with 95% confidence intervals. Proposed outcome measures for a full trial will be presented descriptively (e.g. mean and standard deviations). There are no covariate adjustments in the feasibility analysis.

21. Data monitoring

As this is a low-risk feasibility trial, we will not form a Data Monitoring Committee for the feasibility trial. Instead, given the small scale of the trial, data will be regularly monitored by the TSC and LCTC.

A trial monitoring plan will be developed detailing the internal processes carried out at LCTC. Details on the data cleaning process will be included in a Data Entry and Cleaning Manual (DECM). During data processing there will be checks for missing or unusual values (range checks) and for consistency within participants over time. Other data checks relevant to patient rights and safety will also be regularly performed as per LCTC processes. Any suspect data will be returned to

the site in the form of data queries. Trained staff members at site will respond to queries and provide an explanation/resolution to the discrepancies.

We will send data summaries and analyses in confidence to the TSC in advance of scheduled meetings. This will include information on levels of attrition and any issues with non-completion of particular measures. The TSC will review this information and usually during scheduled meetings, recommend any possible modifications to the trial. The chair of the TSC, in consultation with the wider TSC, will discuss the frequency of reports from the senior management group. They will also determine the frequency of the TSC meetings.

22. Harms

We will exclude participants who pose an immediate risk to others to ensure the safety of research and clinical staff. We will request relevant risk information from the referring clinician as part of the referral process and throughout the study. The team are experienced in assessing, formulating, and managing risk in people with SMI. JPC (PI), PF and RG already supervise mental health practitioners in their clinical-academic roles. Senior clinicians will provide regular training and clinical supervision to the support workers and research staff to ensure that risk is effectively monitored, managed, reported to the senior team, and recorded throughout the research. Staff will be expected to follow relevant safe visiting polices and protocols at all times. They will assess risk to ensure that participants are able to attend the dentist without placing themselves or others at risk.

Definition of adverse events

Event type	Description
Adverse events (AE)	*Any untoward medical occurrence or psychological occurrence in a participant to whom the intervention, assessment or qualitative interview has been administered which does not necessarily have a causal relationship with the intervention. An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease in any participant (including those in an untreated control group), whether or not considered related to the intervention/assessment or qualitative interview.*
Serious Adverse Event (SAE)	*A SAE event is any untoward medical occurrence that:* *- results in death* *- is life-threatening* *- requires inpatient hospitalisation or prolongation of existing hospitalisation;* *- results in persistent or significant disability/incapacity* *Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event, which*

	hypothetically might have caused death if it were more severe. Examples of SAEs include: i) Incidents of self-harm which have been associated with an A&E admission; ii) Increase in the severity or frequency of symptoms that results in a visit to A&E when an outpatient; and iii) deterioration in mental health resulting in hospitalisation. Given the population, SAEs are expected to occur within the trial and will be carefully monitored and reviewed.
Related serious adverse events (RSAR)	*An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to the intervention, assessment or qualitative interview, based on the information provided.*
Related unexpected serious adverse events (RUSAE)	*These are RSAR that are not anticipated to occur as part of the study. They unexpected, serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to the intervention, assessment or qualitative interview, based on the information provided.*

Reporting of adverse events

All AEs / SAEs related to the intervention or trial protocols that occur between baseline and the end of an individual's participation in the study will be recorded in their participation notes, in the appropriate section of the trial CRF, and the study AE / SAE log kept by the chief investigator, site leads, and trial manager. Any contacts completed as part of the intervention will be recorded in participant's medical notes, including a summary of any AE / SAE.

Research and clinical trial staff will be required to report any SAEs immediately and within 24 hours of becoming aware of the event using a set reporting template. The chair (or in their absence, deputy chair) of the TSC will independently review all SAE. The chair will discuss any RSAR / RUSAE with the wider TSC who can then recommend pausing the research while an investigation is completed and learning implemented, or stopping it completely. The chief investigator will notify the REC and funder of any RSAR / RUSAE as soon as possible, but within 15 days of becoming aware of these as per HRA guidance.

The chief investigator will also review all SAE to assess whether they are likely to be the result of any aspect of the trial procedures or intervention (i.e. RSAR / RUSAE). In cases of immediate and obvious concerns about participants' health or safety, the chief investigator may employ urgent safety measures and immediately stop the trial, notifying the research ethics committee (REC) of this decision immediately over the telephone and within three days in writing (as per HRA guidelines).

Given the target sample of people with SMI, we expect there to be some SAEs relating to life-threatening behaviour (i.e. suicide attempts) across both arms of the project. The TSC, trial management team, and Sponsor will monitor and review the number of SAE in the two arms of the trial. Should we record considerably higher rates of SAE in either arm, the TSC will convene

and may recommend pausing the research whilst investigating further or stopping it completely. Due to the increased number of planned participant contacts in the intervention arm (*n*=6), compared to the TAU arm, we may identify a greater number of SAE through increased monitoring in the treatment arm. Therefore, an unequal distribution of SAE will not automatically act as stopping criteria, but would be carefully monitored, reviewed, and actioned as appropriate.

23. Auditing

There are no planned audits from external organisations. However, data from the project may be audited at any point by relevant agencies from the participating NHS Trusts or Universities. We will make this clear to all participants before they agree to take part in the study. The trial management team will monitor study protocol adherence. The TSC and Sponsor will also be able to request audits be undertaken.

24. Research Ethics Approvals

We will obtain IRAS and local Research & Development approvals prior to the start of data collection.

25. Protocol Amendments

Changes to the protocol will require an amendment submitted to the responsible NHS REC. Major alterations to the protocol will also require discussion with the funder and TSC. Please see amendments tale in appendices for information regarding previous drafts of the protocol.

26. Consent

All participants will be given at least 24 hours to decide whether they would like to take part in the trial. The team will provide service users with information about the study via a participant information sheet. They will also have the opportunity to ask questions of the research team and their clinical service. All participants will provide informed consent to take part in the trial. This will be either in the form of a written consent form, which the person will initial and sign, or through audio-recorded consent. We will only use audio-recorded consent for remote assessment sessions or when the client experiences some disability that would prohibit written consent. Only people who provide informed consent will be included in the study.

27. Confidentiality

Each participant will be assigned a randomisation number, allocated at entry to the study, for use on trial documents and all information stored on the electronic database. The research team will make a separate confidential record of the participant's name, date of birth, contact details, and participant

number, to permit identification of all participants enrolled in the study, for the purposes of additional follow-up. Records will be securely stored (password protected) on a secure server at the participating NHS Trusts and Universities, separate to research data. All other information will be anonymised and stored separately to information containing personal details. All hard copy data relating to participants will be stored in locked filing cabinets. Identifiable data on portable devices (e.g. audio recorders, etc.) will be encrypted using encryption software and deleted after being uploaded to a secure server. Access to personal data will be restricted to members of the research team.

28. Declaration of interests

Paul French sits on the NIHR HTA prioritisation committee B and is joint adult mental health clinical lead at Greater Manchester CRN. Rebecca Harris sits on the NIHR Health Services and Delivery Research Funding Committee and is part-time Deputy Chief Dental Officer for NHS England. David Shiers is expert advisor to the NICE centre for guidelines; Board member of the National Collaborating Centre for Mental Health (NCCMH); Clinical Advisor (paid consultancy basis) to National Clinical Audit of Psychosis (NCAP); views are personal and not those of NICE, NCCMH or NCAP. The team have no other declarations of interest to report.

29. Access to data

Only the direct research team will have access to personal data. Study material and data may be accessed by individuals from the participating Universities and NHS Trusts, or regulatory authorities for auditing and monitoring purposes. Following publication of the trial results, we will make suitable arrangements for anonymised data to be available from the Research Team, in line with NIHR data sharing guidance.

30. Ancillary and post-trial care

Taking part in this trial will not prevent participants accessing support and care around their mental or oral health as part of their treatment as usual. The study may prompt greater consideration of oral health problems in people with SMI in both arms. At the end of their involvement in the study (i.e. after the nine month assessment), we will provide all participants with a debriefing information pack on where and how they can access support around accessing dental services. We will also share this information with the referring clinical team to further facilitate support around accessing dental care. The information pack was co-developed with our PPI panel members.

31. Dissemination policy

We will disseminate the findings widely across all stakeholders (clinical, academic, voluntary sector, service users, carers), ensuring that it is appropriate for and tailored to diverse audiences

in collaboration with the PPI committee, and throughout the lifetime of the project. Specific outputs/dissemination plans could include:
- Papers on feasibility in high-impact academic journals (e.g., Journal of Dentistry, Lancet Psychiatry, British Journal of Psychiatry).
- Lay articles on websites, magazines, and leaflet for charities. Bipolar UK, Bipolar Scotland, Rethink, SANE, McPin, and NSUN have already agreed to disseminate. We will continue to build links with local and national organisations to promote the study findings through their networks.
- Presentations at national and international academic conferences for academics, service users, carers, and clinicians.
- Project-specific website and Twitter feed, including lay and expert summaries.
- Closing the Gap UKRI Network will disseminate the findings via their website, Twitter, and YouTube accounts.
- A full report for NIHR HS&DR.
- End of project dissemination events in participating NHS trusts.
- Two national online dissemination events (one in the middle and one at the end of the project) to influence national awareness of research.
- Accessible summary to participants and services in multiple languages and infographic for low-reading ability, developed in collaboration with the PPI panel.
- Dissemination through the oral health in SMI network and resultant consensus statements that we are currently developing through UKRI funding.
- We will ask participants if they know any organisations who might be interested in hearing about the results to create a snowball effect.
- We will liaise with dental professional network chairs, dental and mental health commissioners, NHS England, British Dental Association Executives, Dental Bodies Corporate, policy makers, mental health special interest groups, and national advisory panels to ensure effective dissemination and awareness of the study.
- Collaborate with Royal Colleges (e.g. nursing, psychiatry), societies (e.g. British Psychological Society, British Association of Social Workers) to ensure integration of findings into policy and guidelines.
- Meetings with NHS Trust senior management teams, services managers, service leads, and clinicians to ensure awareness and integration in service planning.

Based of PPI feedback, we intend to share progress and the findings of the research with participants using newsletters, social media (a project account), and a study webpage. We will meet regularly with our PPI panel to revisit and review this strategy, and co-produce relevant outputs. Findings will be shared through various mediums, including videos, animations, and infographics. We will produce complimentary low reading ability versions of the infographics. We have budgeted for the translation of resources into other languages. We will hold free end of trial events at the three localities. We will place recordings of these online (with subtitles) for ease of access. In cases where a participant is unable to access the aforementioned information, a member of the research team will offer to share the findings in a 1:1 conversation via telephone or in person.

The primary product from this study will be a refined manual for the link work intervention and associated training materials. This will include best practice guidance when enabling people with

SMI to attend routine dental appointments. Following the research, we will apply for funding to conduct a definitive trial. Depending on the findings, we will then make the manual and training resources freely available for services, mental health staff, dental staff, and service users nationally. An emphasis on co-production and PPI through each stage of the project will ensure that all outputs are acceptable to different stakeholder groups. Awareness of the outputs will be made using the dissemination strategy.

There is currently little specific support available for people with SMI around their oral health. Additionally, there is little guidance for mental health services to support patients to attend dental services. The current intervention could be readily deployed into mental health services. A workforce of support workers are already in place. They already support patients around other aspects of their physical health (e.g. diet, exercise) and help them to attend appointments. This is therefore a logical extension of their usual duties and responsibilities. If shown to be effective, the team are well placed to facilitate the adoption of the intervention in the three participating Trusts and, more widely, across the NHS. French (CI) is regional clinical lead for early intervention in psychosis and joint national clinical advisor to the national clinical audit of psychosis. Harris (co-PI) is the deputy chief dental officer and can ensure uptake of findings within NHS dentistry.

32. Trial management and committees

Our team is uniquely qualified to deliver this project to time and budget. JPC (co-PI) is a clinical academic with joint NHS/academic post specialising in SMI and will co-lead the project, he will oversee recruitment in LSCFT. RH (co-PI) is the Deputy Chief Dental Officer in England and an expert in Dental Public Health with two successfully completed HS&DR awards. She will offer senior mentoring to JPC and supporting the overall management and coordination of the project. FL is Director of the Spectrum Centre for Mental Health and is an expert in mixed method evaluations of complex interventions in SMI [90] and will co-lead the qualitative work package. KB is a Professor in Clinical Psychology and expert in SMI behaviour change interventions delivered through support workers [68] and will lead the intervention's development. VA is a clinical academic dentist at Leeds University bringing learning from the Three Shires Study [27], systematic reviews, and clinical assessment/dental examination. He will lead the systematic review, supporting clinical supervision of the dental therapist, and the BSA data application. RG is the Director of the Nursing Research Unit taking the role of site lead at GMMH. PF is a clinical academic and Regional Clinical Lead for Early Intervention in Psychosis who will be site lead of PCFT. GB is a statistician experienced in dental health trials at Liverpool University and LCTC. LL is a qualitative researcher in Dental Public Health who will co-lead the qualitative work package. SP is Clinical Lead of Special Care Dentistry in LSCFT and will support supervision and management of the dental therapist. CL is PPI lead has lived experienced of SMI and being a supporter worker, and is PPI lead for the project. DS is a carer and champion for physical health in people with SMI and will support all PPI activities and intervention development.

We have costed three research assistants (RA1-3 Band 4, 80% FTE) to facilitate recruitment, assessment, and data entry (one per NHS site). RA1 will be in post for 20M to facilitate

screening and data extraction of the systematic review. RA2 and RA3 will be costed for 16M. Three support workers (SW 1-3; Band 4; 16M) will deliver the intervention and are costed as Excess Treatment Costs. JPC will supervise RA1 and SW1 at LSCFT. RG will supervise RA2 and SW2 at GMMH. PF will supervise RA3 and SW3 at PCFT. We have costed Dental Therapist time to conduct and score the dental examination (Band 5; 60% FTE; 16M), who will be supervised by SP and VA. Supplementary training and supervision will be provided by the senior team. The trial management team will consist of the project PIs and co-investigators, and will be responsible for overseeing the general design, implementation and running of the study. The management team will meet at least monthly, with the understanding that some members may attend less frequently.

Liverpool Clinical Trials Centre (LCTC) have been involved in developing the research plan along with the lead and co-applicants. They have provided methodological and statistical expertise and guidance. The data manager will review the participant data in the secure trial database and liaise with sites to ensure the resolution of queries. LCTC will provide robust data management processes and effective monitoring and reporting activities (to comply with GCP and regulatory requirements). LCTC will be responsible for eCRF development, data entry, monitoring, and data cleaning. LCTC will develop and maintain the database. A statistical RA (20% FTE, 24M) at Liverpool CTU will undertake data cleaning, attendance at meetings, report writing and final analysis. Supervision and training of trial-specific personnel will be undertaken by GB and senior LCTC staff.

The TSC will be comprised of experts in treatment evaluation, severe mental illness, dentistry, and access, and individuals with lived experience. 75% of the members attending each TSC meeting have to be independent of the trial. Independent members must:

- Not part of the same institution as any of the applicants or members of the project team.
- Not part of the same institution that is acting as a recruitment or investigative centre, including Patient Identification Centres (PIC), identifying and referring patients to a recruitment or investigative centre (In both cases above ‘not part of the same institution’ means holding neither a substantive or honorary contract with said institution).
- Not related to any of the applicants or project team members.
- For the Chair only; not an applicant on a rival proposal.
- It is recognised that independence status may change during the duration of the trial.

The TSC will meet at least twice annually and have a role in providing advice to the project team, sponsor, funder, and other relevant bodies, regarding all aspects of the conduct of the trial. In particular, they will guide decisions regarding serious adverse events, and help in troubleshooting issues related to recruitment during the course of the study. The TSC can meet more frequently at the discretion of the chair. We will invite a representative of the sponsor to TSC meetings who will also receive copies of the TSC reports.

The Patient and Public Involvement (PPI) Advisory Group (PPIAG) will comprise of people with lived experience (n = 5) and independent mental health support workers (n = 4) recruited through participating NHS trusts (PCFT, LSCFT, GMMH), mental health charities, and Spectrum Connect (a database of people with SMI who have agreed to be contacted about such opportunities), ensuring representation from different ethnic and sociodemographic backgrounds,

and genders. CL will speak with people individually, share information about the PPI role and the project, and answer any questions. He will help them understand the role that they would be undertaking and the value of their perspective. This will enable people to make an informed decision of whether to become a panel member.

Eight quarterly panel meetings will allow for discussion of liaison strategies with services, recruitment planning, sensitivity training for research and clinical staff, co-development of training materials for staff, discussion of operational and implementation issues, the refinement of the intervention, and dissemination outputs. PPI panel members will be active stakeholders making key decisions around the project, weighing up the advantages and disadvantages of certain choices. We will ensure that members all members are supported and given the opportunity to participate, making necessary adaptions where necessary (e.g. translator, large font handouts etc.). We will offer reimbursement for time and travel expenses (based on INVOLVE rates). They will receive £40 reimbursement per two-hour PPI session, plus up to 40 miles travel expenses (equivalent to £18 in travel expenses per visit). Where access is difficult, members may attend virtually via Teams/Zoom, or over speaker phone. At times, we will invite research (e.g. research assistants, dental therapist) and clinical (e.g. link workers) staff to attend PPI meetings for shared learning and discussion, whilst carefully ensuring that there is no breaking of the blind. We have costed in some time of a graphic designer who will meet with the PPI panel to co-produce an InfoGraphic of the study findings for dissemination. We will work with the PPI panel to identify any training needs during the project, which will be offered by an appropriate team member. This could include a general introduction to the research cycle or more detailed information on any aspect of the project protocols (e.g. how the dental examination works). We have costed in for three training sessions across the project. The team are experienced at offering training to service user panels and co-developing accessible outputs around protecting the oral health of people experiencing SMI (see www.rightfromthestart.com for examples).

CL will chair the PPI panel meetings. DS (PPI carer) is a family member and retired GP and will offer a carer perspective at meetings. With member's consent, an administrator will take minutes of the PPI panel meetings so that no information is lost. PPI discussions will be brought and considered within management and steering group meetings. CL will also make a systematic record of key decisions and how this influenced the delivery of the trial and intervention. The team has an excellent record of co-development and supporting service users on PPI panels. CL is experienced at leading PPI panels.

33. Embedded qualitative study

We will conduct an embedded qualitative study that draws on the MRC evaluation of complex intervention framework [78]. This highlights the need to identify and address potential challenges that could undermine the conduct of the full RCT and/or the acceptability and delivery of the intervention. The aim is to understand the potential factors impacting (e.g. facilitators and barriers) acceptability and delivery of the support work intervention and project (research aim 5).

In particular, it aims to understand:

a) What determines staff levels of referral
b) Reasons for participation/non-participation during the recruitment process
c) The feasibility of blinding RAs
d) Support worker experiences of and attitudes to delivering the intervention
e) Patient experiences of, and attitudes to, trial participation including any changes in behaviour
f) How to optimize the acceptability and feasibility of a future definitive trial

These findings will be used to further refine the intervention and trial procedures based on staff and patients' feedback, and to inform the design of a definitive RCT [79].

Stages of data collection:

Work *before and during* the feasibility trial will focus on addressing aims a), b) and c) related to trial processes

- Interviews with the three RAs on the acceptability of trial recruitment and procedures
- Interviews with up to 10 service users on the acceptability of trial recruitment and procedures
- Audio-recordings of assessment sessions with RAs to identify potential issues
- Field notes from RAs and support workers.

Work *towards the end of the trial* will focus on aims d), e) and f) to understand the acceptability and feasibility of delivering the intervention

- Interviews with the three support workers at each of the research sites to examine their experience of delivering the intervention, and their views on what works best and least well.
- Interviews with up to 10 relevant stakeholders (staff, managers, commissioners) to understand local factors related to delivery and how this intervention could be implemented into routine practice.
- Interviews with up to 10 patients and/or carers to understand their experiences of participating in the trial and intervention including any subsequent changes in behaviours and/or attitudes, and what potential changes are needed and wanted.

Participants, recruitment and sampling:

All SMI service users deemed eligible for the feasibility study will be able to participate in the qualitative study. All eligible SMI service users will be asked to give permission for assessment sessions to be audio-recorded. The Quintet Recruitment Intervention [80] recommends audio-recording sessions, alongside interviews with recruiters and participants, to identify issues and misunderstandings in the engagement process. If SMI service users do not wish for the session to be audio-recorded the RA will still take some anonymised field notes to reflect on their views of the session.

During the recruitment session for the trial feasibility, people with SMI will be given information about the qualitative study and asked for permission to contact them about participating at a later date by LL (joint-qualitative lead). LL will contact consenting participants to talk through the study and will give them time to ask questions. LL will then arrange an interview date at a convenient time and place. Written consent will be gathered prior to the interview. All relevant staff (RAs, support workers, dental therapist) involved in the trial process will be invited to participate in the qualitative study. They will be given a PIS at the outset of the study and LL will arrange to talk over the study and give them time to ask any questions. LL will then arrange

an interview date, at a convenient time and place, for those willing to participate. Written consent will be taken prior to the interview.

Determining sample sizes for qualitative research is problematic [81]. Based on experience, we anticipate that a total of 36 interviews will be appropriate to fully understand the factors affecting trial feasibility and the delivery of the intervention. We will purposively sample interviewees to capture different levels of engagement with assessments and the intervention (including those who withdrew). SMI service users will be reimbursed £20 for their time.

Data Collection

All interviews will follow a topic guide developed to address the research questions above and based on the existing literature (such as 82). We anticipate that topic guides will cover:

- For SMI service users in the first stage of data collection: understanding of the PIS and verbal information given during the recruitment session, language used and any uncertainties, reasons for participating/ not participating, under what circumstances would they participate/not participate.
- For SMI users in the second stage of data collection: experiences of participating in the trial, understanding of the intervention, what aspects of intervention was helpful/unhelpful or acceptable/unacceptable, any behavior change as a result of the intervention, potential improvements needed or wanted, reasons for any disengagement or withdrawal.
- For staff in the first stage of data collection: views on the recruitment process, the information give to participants, instances in which they were unhappy or unwilling to recruit eligible services users, their perspectives on barriers to participation.
- For staff in the second stage of data collection: experience of delivering the trial intervention, views about approach, experiences of barriers and facilitators to engagement, opinions on what worked well/less well, any change to their working practice as a result of participating.

The topic guides will be piloted to ensure the questions are understandable and appropriate. The interviews will be audio-recorded with permission and be transcribed verbatim. If participants are not comfortable being audio-recorded, the interviewer will take written field notes. They will take place in community settings (e.g. homes, services) or over the phone/online depending on participant preference, and last ≤60 minutes.

Analysis

LL and FL will analyse data iteratively and concurrently with data collection. This will allow arising topics to be explored in subsequent interviews and allow a dynamic approach to the study in which important findings can be used to iteratively inform the design of the feasibility trial. Thematic framework analysis using a hybrid deductive/inductive thematic approach will be used [83]. Thematic framework analysis is particularly useful for multi-disciplinary team working due to the structured nature of analysis [84]. A framework analysis starts with the familiarisation of transcripts and initial coding of a sample of transcripts by both LL and FL to ensure consistency. Following this, a set of agreed codes will be applied to subsequent transcripts. As the analysis progresses, the codes are categorised and charted into a matrix, which allows comparison between the codes, participants, and the different research sites. Initial themes will be presented to the research team for further development and contextualization within the broader study.

34. Co-development of treatment manual and resources – PPI work.

We will convene four to six PPI stakeholder workshops to refine the intervention and training resources prior to the trial (research aims 1 and 2). RA1 will recruit 5-10 service users with SMI, carers, and support workers from secondary care mental health services and charities, and dental staff from local NHS dentists and special care dentistry services, to each workshop. We will aim to recruit a diverse sample of service users and carers in terms of ethnicity, age, gender and occupation/socioeconomic status. Our recruitment strategy will be informed by the NIHR's equality, diversity and inclusion framework. Ethnic diversity is particularly important given that people from Black and Minority Ethnic backgrounds (BME) are disproportionately likely to be diagnosed with SMI [90]. We will achieve this by targeting recruitment from services in ethnically diverse areas and through previous contacts with mental health organisations representing BME groups. To facilitate participation of those with additional needs, we will ensure our meeting venues are well served by public transport and accessible for those with mobility issues. We will provide taxis for those who need them. We will also invite participants to bring supporters if they wish and provide translators for those who need them. Depending on COVID-19, we may hold workshops remotely and in which case we will ensure that lack of access to technology does not prohibit participation. For example, we will offer phone calls to people who do not wish to use the internet to access meetings.

PPI workshops will be co-facilitated by KB, DS and CL (PPI lead). Feedback will iteratively inform the creation of best practice intervention manual and training resources for support workers when delivering link work to support dental visiting. Co-production will yield prototypes of the intervention manual and later the training resources. The first workshop will be used to orientate people to the project, develop expectations from both participants and the researchers and collaboratively agree group ground rules. Prior to carrying out the second workshop, we will pool existing resources from link work interventions. We will present these to participants using a range of different types of media. For example, as written material to review or short video and/or presentations describing the content. We will ask participants what they like about materials in terms of content or mode of presentation. We will then ask them what additional things we need to include given our focus on oral health. We will make detailed notes with the purpose of capturing the content of the discussion. Following each workshop, we will review feedback and use this to develop the next iterations of the manual and training resources for further comment.

We will work with the service user researcher (CL)/ carer advisor (DS), and PPI panel, to co-develop all information materials to ensure that they are easy to follow and understand. This will include a participant information sheet outlining the inclusion/exclusion criteria, the aims of the study, what taking part would involve, the advantages and disadvantages of taking part, confidentiality of data, information on dissemination, the details of the site RA and senior team members, and relevant complaints procedures. We will ensure that all participants have access to the participant information sheet prior to taking part. Copies will be sent via letter, email, in person, or through the referring clinical team. We will also generate plain-English recruitment posters for patients and leaflets for clinicians at recruiting sites. We have previously found that these help to generate referrals and support access to research.

Senior investigators (JPC, RH), the trial manager, and the local independent research and development office (LSCFT, PCFT, GMMH) can answer any queries, concerns, or issues that participants might have with the project, intervention, or assessments, which will be clearly stated in the participant information materials. In the event that participants would prefer to talk to another agency, we will signpost them to their secondary care mental health team or the Patient Advice and Liaison Service (PALS). RAs and support workers will remind participants of their options, which will also be stated on dissemination materials, whilst emphasising the importance of maintaining blinding. At each assessment session, participants will be provided with a wallet-sized card containing the details of helplines (e.g. MindInfo Line, Samaritans, SANEline, NHS111). This will also remind participants to direct concerns about their mental health to their clinical service and to contact accident and emergency services or a crisis team in cases of emergency. Participants will have the right to withdraw from the study at any time, without it affecting their routine clinical care. If a participant wishes to withdraw, we will ask for their reasons to understand their experiences. We will ask whether participants to still consent to their existing data being used in the research or removed completely. Participants are able to withdraw from the intervention, but still complete the follow-up assessments and a qualitative interview.

35. Project / research timetable

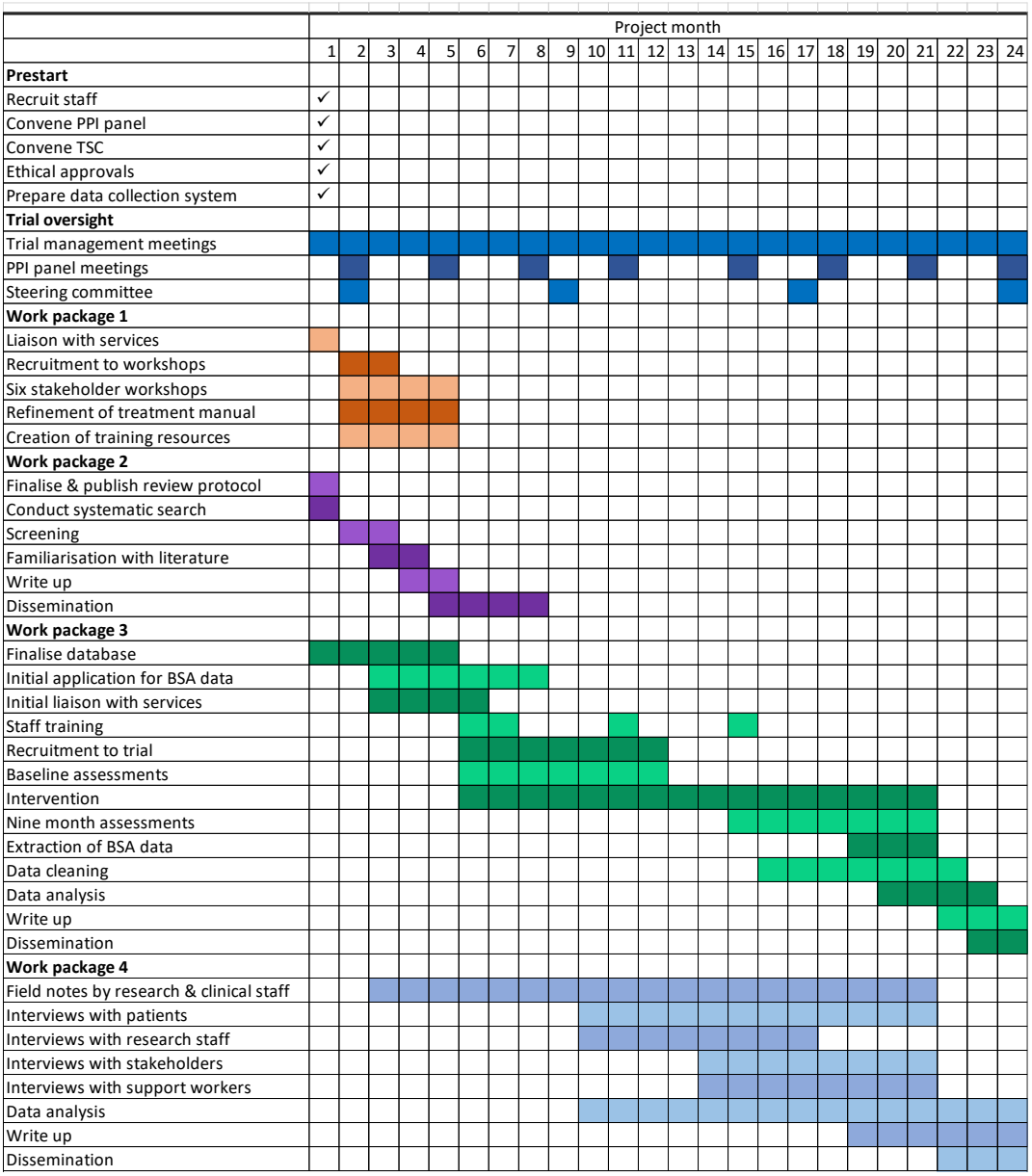


Table 2. GANTT chart

36. Copyright statement

37. References

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Table of amendments to protocol

Protocol number	Date	Main changes made to protocol