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An intervention using link workers to improve dental visiting in people with severe mental illness

Submission date
01/08/2022

Recruitment status
No longer recruiting

Registration date
09/08/2022

Overall study status
Completed

Last Edited
04/08/2025

Condition category
Oral Health

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Severe mental ill health (SMI) affects around 1% of the population. It includes depression, psychosis, and bipolar disorder. People with experience of SMI are more likely to have problems with their teeth and gums. This includes more missing, filled, and decayed teeth than people without SMI. Having poor oral health can impact a lot of everyday activities like eating, speaking and smiling. It can affect how patients see themselves and their mental health.
Dentists can treat many early teeth and gum problems. However, very few people with SMI attend regular dental appointments. Instead, they are more likely to seek help when in crisis and invasive treatments are the only option. Accessing a dentist for people with SMI can be difficult for lots of reasons. People can feel helpless, fearful, or demotivated about attending. They can have difficulty booking, planning, and getting to appointments. They may struggle to pay for or access free dental care. Unfortunately, existing dental initiatives have not addressed the barriers facing this group. They do not help people with SMI to attend the dentist.
To help people with SMI to access dental care this study will use mental health support workers who are already working in the NHS. They will link people receiving care from mental health teams with dental services. The support workers will help people to book, plan, and attend regular dental appointments. They will support patients to apply for financial support. People call this type of support link work. Research has indicated that link work can increase dental visits in people who might not normally attend. Mental health support workers already do link work for other appointments. Link work has been used to help other vulnerable groups of people (e.g. children) around dental care. However, this will be the first use of link work to help people with SMI to attend the dentist.

Who can participate?
People aged over 18 years with a severe mental health difficulty currently accessing secondary care mental health services at the point of referral (e.g. community mental health team, early intervention for psychosis service), but who have not had a routine dental appointment in the past 3 years.

What does the study involve?
Participants will be randomly allocated to receive treatment as usual or treatment as usual plus the link work intervention. This will be decided by chance. The researchers will measure how often people in both groups visit the dentist. They will also assess the state of their teeth and gums. They will collect this data when people come into the study and after 9 months. They will offer interviews to patients and staff involved in the study to understand how they found their involvement.

What are the possible benefits and risks of participating?
The intervention aims to support people to access dental services. However, it is currently untested, which is the reason for doing the research.

When is the study starting and how long it is expected to run for?
April 2022 to April 2024

Who is funding the study?
The National Institute of Health Research (NIHR) Health and Social Care Delivery Research (HS&DR)

Who is the main contact?
Dr Jasper Palmier-Claus, j.palmier-claus@lancaster.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Jasper Palmier-Claus

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
304696

ClinicalTrials.gov (NCT)
NCT05545228

Protocol serial number
IRAS 304696, CPMS 53409

Study information

Scientific Title
An intervention using link workers to improve dental visiting in people with severe mental illness: The Mouth Matters in Mental Health Trial

Study objectives
To investigate the feasibility and acceptability of a link work intervention to increase planned dental care visits for patients with severe mental illness, and through this improve their oral health. The aims are:
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 severe mental illness (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 severe mental illness engage with a link work intervention
6. To understand the potential factors impacting (e.g. facilitators and barriers) acceptability and delivery

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, Wales Research Ethics Committee - 2

Study design
Feasibility single-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
People with severe mental health difficulties accessing secondary care mental health services who have not been to the dentist in the past 3 years

Interventions
The researchers will recruit 84 participants from three NHS Trusts in North West England. Randomisation will be via a secure 24-hour web-based randomisation programme managed centrally by Liverpool Clinical Trials Centre (LCTC). Participants will be allocated to one of the

two groups, with a 1:1 ratio, stratified by site. 42 will be randomly allocated to treatment as usual (TAU). 42 will receive treatment as usual plus a link work intervention to support access to dental services. The link work intervention will consist of six sessions of bridging and advocacy delivered by a grade 4 non-clinician (NHS banding) over 9 months.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility outcomes measured at 9 months follow-up:
1. Recruitment rates: the ability to randomise 84 participants to target in a 7-month recruitment window. Green ≥80%. Amber 60-79%. Red ≤59%.
2. Visiting data: percentage of participants with available data on dental visiting via self-report or BSA. Green ≥90%. Amber 60-89%. Red ≤59%.
3. Clinical exam: percentage of participants completing the dental examination. Green ≥80%. Amber 60-79%. Red: ≤59%.
4. Adherence to intervention: percentage of participants receiving intervention ≥1 sessions during a 9-month window. Green ≥80%. Amber 60-79%. Red ≤59%.
5. 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.
6. Safety of intervention: monitoring and review of research-related serious adverse events (SAEs). The trial steering committee (TSC) will oversee SAEs across treatment arms. The researchers will discontinue the trial if the intervention or procedures elevate risk.

Key secondary outcome(s))
Proposed primary outcomes for definitive trial:
1. Planned dental appointment as measured by self-report at baseline and 9 months
2. Planned dental appointment as measured by business service authority data for the 9-month intervention window and recorded at follow-up

Self-report assessments at baseline and 9 months:
1. Orofacial pain measured using the gold-standard Brief Pain Inventory – short form
2. Pain-related disability measured using the Manchester Orofacial Pain Disability Scale
3. Oral health related quality of life measured using the Oral Health Impact Profile
4. Self-efficacy around dental visiting measured using the items: 'How confident are you that you will be able to attend a dental appointment?' (1, no confident; 7, very confident)
5. Self-esteem using the Rosenberg Self-Esteem Scale (RSES)
6. Dental anxiety using the Modified Dental Anxiety Scale
7. Depression using the Patient Health Questionnaire
8. Quality-adjusted life year using the EuroQol 5 Dimension (EQ-5D-5L)
9. Access to free or subsidised dental care
10. The number of completed routine dental visits
11. Oral health self-management, namely the use of brushing, flossing, and mouthwash

Dental examination at baseline and 9 months:
1. Decayed, missing or filled teeth scores by dental examination
2. Pulpal involvement, ulceration due to trauma, fistula, and abscess by dental examination
3. Modified Plaque Score by dental examination

Business services authority (BSA) data on dental attendance, access to free dental care, treatment, and distance travelled to appointment. BSA variables will be assessed for the 9-month intervention window and recorded at follow-up.

Completion date
01/04/2024

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Able to provide informed consent
3. Receipt of care from a Community Mental Health Team (or equivalent service) or Early Intervention Team at the point of referral
4. No routine and planned dental appointment in the past 3 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 3 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. The researchers 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.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
79

Key exclusion criteria
1. Inpatient status on a psychiatric or secure ward. The researchers will allow participants in supported living to take part as long as they are in receipt of care from a Community Mental Health Team (or equivalent service) or Early Intervention for Psychosis Service
2. 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 1 month’s time (or a time period agreed in collaboration with the individual) to

determine if the risk has subsided to a point where they are now eligible.
3. Enrolled in a dental trial

Date of first enrolment
03/10/2022

Date of final enrolment
01/05/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lancashire & South Cumbria NHS Foundation Trust
The Lantern Centre
Vicarage Lane
Fulwood
Preston
United Kingdom
PR2 8DW

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Harrop House
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-lyne
United Kingdom
OL6 7SR

Sponsor information

Organisation
Lancaster University

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Following the publication of the trial results, the researchers will make suitable arrangements for anonymised data to be available from the research team, in line with NIHR data sharing guidance. The anonymised quantitative data are/will be available upon request from Jasper Palmier-Claus (j.palmier-claus@lancaster.ac.uk) for 5 years from the end of the study. The researchers will be obtaining consent from participants to this effect.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/08/2025	04/08/2025	Yes	No
Protocol article		08/09/2023	11/09/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes