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Testing an intervention to promote good oral health in people with severe mental illness

Submission date
16/02/2026

Recruitment status
No longer recruiting

Registration date
19/02/2026

Overall study status
Ongoing

Last Edited
20/03/2026

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Tooth decay and tooth loss can have a big impact on general health and quality of life, and cause pain and difficulty when eating. This can reduce self-esteem and lead to problems in everyday life. People living with severe mental illness are much more likely to have tooth decay and to have lost their natural teeth. This can be due to several challenges related to mental illness, their use of medication and lack of support from health services. Oral health is often a low priority in caring for people with mental illness. We aim to create a support system in mental healthcare settings that will support them to maintain regular oral hygiene and help them enjoy good oral health.
We have already talked to people who experience mental ill health, their families and carers and mental health staff. Through several workshops with created a support system together to help people with mental ill health look after their teeth and mouth health.
In this study we will ask people who experience mental ill health to test out this support system. We will ask them what they thought of it and if they found it helpful or not. We will ask people to tell us how often they brushed their teeth before and after receiving support, and about their awareness of how to prevent dental diseases. We will also look at costs to see how much this system might cost the NHS.

Who can participate?
Adults aged over 18 years with a diagnosis of psychosis, schizophrenia, schizoaffective disorder, bipolar disorder or other non-organic psychosis can take part in the study. They should feel comfortable speaking English.

What does the study involve?
Once they have agreed to take part in the study, participants will meet a researcher who will collect questionnaire data on their mental and oral health. All participants will then receive advice on maintaining good oral health from a mental health professional in a separate appointment. The conversation should take around X minutes. Participants will be invited to another appointment at 3 and 6 months when they will be asked to complete some of the questionnaires again with a researcher. Some participants will also complete an interview with a researcher at 6 months if they opt in (5 participants from each NHS trust).

What are the possible benefits and risks of participating?
Participants's oral health may benefit from the advice they were given. We don't anticipate any significant risks to participants, but some may find the topic of oral health distressing or sensitive.

Where is the study run from?
The study runs from two NHS trusts: Sheffield Health Partnership University and Tees, Esk and Wear Valleys (TEWV) (UK)

When is the study starting and how long is it expected to run for?
February 2026 to August 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Masuma Mishu, masuma.mishu@ucl.ac.uk

Contact information

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Principal investigator, Scientific

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Integrated Research Application System (IRAS)
361009

Central Portfolio Management System (CPMS)
70872

Study information

Scientific Title
Enabling Service Users with Severe Mental Illness to Learn about and Engage (SMILE) with Good Oral Health: a feasibility and acceptability study of an intervention aimed at improving the oral health of people with severe mental ill health

Acronym
SMILE

Study objectives
The main aim of this project is to explore the acceptability and feasibility of SMILE intervention (SMILE intervention has been co-produced with the aim to improve oral health in people with SMI).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/01/2026, West Midlands - South Birmingham Research Ethics Committee (2 Redman Close, London, E20 1JQ, United Kingdom; N/A; southbirmingham.rec@hra.nhs.uk), ref: 25/WM/0235

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Oral health in people with severe mental illness (SMI; including psychosis, schizophrenia, schizoaffective disorder, bipolar disorder or other non-organic psychosis)

Interventions
The oral health intervention was co-produced through four co-production workshops and PPIE meetings with service users, carers, mental health and dental health professionals.

It will be delivered by a mental health professional who will provide advice on the importance of oral health and how to maintain one's oral hygiene.

Mental health professionals will be trained to deliver the intervention. A training manual and a flipchart will be provided to guide the mental health professionals through intervention delivery.

Intervention Type
Behavioural

Primary outcome(s)
1. Acceptability and feasibility of delivering the intervention measured using the study record (e. g. number of potential participants who are screened, number of those who participate, and those who drop out), at 6-month follow-up

2. Acceptability and feasibility of delivering the intervention measured using survey with participants and professionals who delivered the intervention at 6-month follow-up

Key secondary outcome(s))
1. Oral health measured using a bespoke oral health questionnaire (capturing oral health and dental access; tooth brushing habits and frequency; dietary sugar intake frequency) at baseline, 3-month follow-up, 6-month follow-up

2. Oral health-related quality of life (OHRQoL) measured using Oral Health Impact Profile-14 (OHIP-14) at baseline, 3-month follow-up, 6-month follow-up

3. Health-related quality of life measured using EuroQol EQ-5D at baseline, 3-month follow-up, 6-month follow-up

4. Economic evaluation measured using a bespoke healthcare service use questionnaire at baseline, 3-month follow-up, 6-month follow-up

Completion date
31/08/2026

Eligibility

Key inclusion criteria
1. Have a diagnosed severe mental illness (SMI): psychosis, schizophrenia, schizoaffective disorder, bipolar disorder or other non-organic psychosis (ICD codes to include are F20-29, F30-F31, F32.3, and F33.3).
2. Aged 18 years or above.
3. Comfortable communicating in English

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Those in an acute psychiatric ward
2. Those who lack capacity to participate in the study guided by the Mental Capacity Act (MCA) 2005
3. Those who are not able to communicate in English

Date of first enrolment
17/02/2026

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital
Edward Pease Way
Darlington
England
DL2 2TS

Study participating centre
Sheffield Health Partnership University NHS Foundation Trust
Centre Court
Atlas Way
Sheffield
England
S4 7QQ

Sponsor information

Organisation
Sheffield Health and Social Care NHS Foundation Trust

ROR
https://ror.org/05cn4v910

Funder(s)

Funder type

Funder Name
Sheffield Partnership University NHS Foundation Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available