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Improving uptake of cervical screening in people with severe mental illness using tailored text message reminders

Submission date
05/10/2023

Recruitment status
No longer recruiting

Registration date
22/10/2024

Overall study status
Ongoing

Last Edited
08/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
In the United Kingdom, there's a program called the Cervical Screening program that offers cervical screening to women and individuals with cervixes aged 25 to 65. They get invited for this screening every three years if they're between 25 and 49 years old, or every five years if they're between 50 and 64 years old. These invitations usually come in the form of a letter and, in most cases, a text message reminder.
However, a study from 2018 discovered that people with severe mental illness (SMI), especially those aged 45 to 64, were 20% more likely to miss their cervical screening within the recommended timeframe compared to those without SMI.
To help boost the participation of individuals with anxiety about attending cervical screening, mental health service users and healthcare professionals have created an informative tool, like a pamphlet. You can find it on the government's official website (gov.uk), as a downloadable pamphlet on the Jo's Cervical Cancer Trust website, and as an animation on YouTube. The current invitation letter or text message reminders don't include links to these helpful resources. The study aims to test if it is possible to run a trial where people receive either an enhanced text message reminder with a link to the tool or the standard text message that they usually get and see if this increases the number of people who read the information and attend screening.

Who can participate?
People with SMI who are overdue for cervical screening aged 24 - 64 years

What does the study involve?
Participants will be randomly assigned to receive either an enhanced text message reminder with a link to the tool (that's the intervention), or the standard text message that they usually get (that's the control). This pilot trial will be overseen by a company called iPLATO, which the NHS has hired to do research and send out text messages.
Local doctor's offices will identify people who are eligible for this trial and give the names to iPLATO. Then, iPLATO will randomly assign these participants to either the intervention or control group and send the appropriate text message accordingly. Within these text messages, participants will have the option to opt out of the study. Additionally, participating local doctor's

offices and local charities will alert patients to the study so that they can opt out if they wish. After the study is done, local doctor's offices will add extra data about participants (e.g. age and ethnicity) to the data and send it to the research team.
If participants in the intervention group go for screening, they'll be asked if they used the information and what they thought of it. For the control group, since the information is already publicly available on the NHS screening website and provided on the invitation letters sent to patients who are due for their cervical screening, they'll be asked if they looked it up before attending screening.
This pilot trial will last for 9 months and is being funded by the National Institute of Health and Social Care Research Policy Research Unit in Behavioral and Social Sciences. Its purpose is to help decide whether this improved cervical screening reminder can increase participation among people with SMI.

What are the possible benefits and risks of participating?
Possible benefits are that this text message reminder may help people with SMI to attend for cervical screening reducing their risk of cervical cancer. This is a very low-risk intervention. The information leaflet is already available in the public domain and text message reminders are widely used by GP practices for cervical screening.

Where is the study run from?
Newcastle University (UK)

When is the study starting and how long is it expected to run for?
March 2023 to August 2025

Who is funding the study?
National Institute of Health and Social Care Research Policy Research Unit in Behavioural and Social Sciences (UK)

Who is the main contact?
Beth Nichol, beth.nichol@newcastle.ac.uk

Study website
https://behscipru.nihr.ac.uk/our-projects/optmise-trial-improving-uptake-of-cervical-screening-in-people-with-severe-mental-illness/

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
323832

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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Study information

Scientific Title
Behavioural SMS reminders with link to decision tool to improve uptake of cervical screening amongst people with severe mental illness (SMI) that are overdue: a pilot randomised controlled trial

Acronym
OPTIMISE

Study objectives
To establish the feasibility of conducting a randomized controlled trial (RCT) that compares enhanced SMS cervical screening reminders with usual SMS reminders to increase screening uptake among people with SMI that are overdue i.e. did not attend (DNA)/non-responders.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/03/2023, West Midlands - Edgbaston Research Ethics Committee (3rd Floor, Barlow House, Manchester, M1 3DZ, United Kingdom; +44 207 104 8357; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0037

Study design
Pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention, Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Prevention of cervical cancer in patients with severe mental illness

Interventions
Participants randomised to the intervention arm will receive a text message reminder that has been developed with wording framed around social norms (informed with the input of patient representatives and their carers). It will include a link to an information leaflet that has been tailored to and developed by patients with SMI and an animation explaining the leaflet.

Participants randomised to the control arm will receive the usual standard text message reminder about booking an appointment for cervical screening.

Participants will be randomised using a random number generator. Participants will be allocated intervention group 1:1, stratified by age.

Intervention Type
Behavioural

Primary outcome measure

1. Number of eligible participants per practice identified from a search of GP records (searched for and screened by practice staff)
2. Number of participants that opt out of the study within 14 days of the study invitation and research information sheet recorded by iPLATO
3. Number of invalid phone numbers recorded in GP records during the recruitment window recorded by iPLATO
4. Number of missing phone numbers recorded in GP records during recruitment window recorded by iPLATO
5. Number of participants where Cervical Screening status is missing in GP records at 18 weeks post-intervention recorded by iPLATO
6. SMS delivery status (recorded by iPLATO) recorded at the intervention date
7. Number of participants who access the tool/ click on the link in the text (and the no. times they click on the link) recorded at the intervention date
8. Costs incurred recorded via resource use proforma completed by iPLATO and GP staff at the end of the study

Secondary outcome measures
Proportion of women in each arm who arrange and attend a CS appointment within 18 weeks of the SMS reminder being sent. Age, gender, ethnicity and index of multiple deprivation (IMD) decile, date of last CS, will be measured as co-variates

Overall study start date
23/03/2023

Completion date
14/08/2025

Eligibility

Key inclusion criteria
1. Women and people with a cervix who are diagnosed as having severe mental illness and are overdue their cervical screening test.
2. Aged 24 - 64 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
24 Years

Upper age limit
64 Years

Sex
Female

Target number of participants
88

Total final enrolment
150

Key exclusion criteria
1. People who are exempt from cervical screening and have declined to receive the usual SMS text message reminders will be excluded
2. Those the general practitioner considers it inappropriate to approach
3. Patients inappropriate to approach (patients who are receiving palliative care, have declined screening when offered by their GP in the last 12 months, and have submitted a cervical screening opt-out form)

Date of first enrolment
25/11/2024

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS South East London Integrated Care Board
Southwark Council
160 Tooley Street
London
United Kingdom
SE1 2QH

Sponsor information

Organisation
Newcastle University

Sponsor details
Faculty of Medical Sciences, The Medical School, Newcastle University, Framlington Place
Newcastle Upon Tyne
England
United Kingdom

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Sponsor type
University/education

Website
http://www.ncl.ac.uk/

ROR
https://ror.org/01kj2bm70

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

Publication and dissemination plan
• The trial protocol will be made publicly available upon the Open Science Framework upon HRA approval having been obtained.
• Upon completion of the trial, the data will be analysed and tabulated and a manuscript prepared which will published in open access journals
• DHSC will have 28 days to review publications before they are published.
• NIHR will be acknowledged within the publications
• Patient representatives and participating practices involved in the study will receive a short summary of the research findings. Practices are welcome to share this with the individuals who

participated (as the trial team will not have names and addresses) and/or post the summary on their websites. A link to the unit's project website has been added to the research information sheet and a lay summary will be provided there at the end of the study.

Intention to publish date
01/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and or analysed during the current study are not expected to be made available as we are not obtaining consent from participants to do so.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Patient notification poster version 2	08/10/2024	14/10/2024	No	No
Protocol (other)	Version 5	08/11/2024	14/11/2024	No	No