ISRCTN24746936 https://doi.org/10.1186/ISRCTN24746936

CONNECT: using electronic devices (e.g. smartphones, smartwatches) to predict relapse of psychosis

Submission date
20/02/2023

Recruitment status
Recruiting

Registration date
30/10/2023

Overall study status
Ongoing

Last Edited
30/12/2025

Condition category
Mental and Behavioural Disorders

[X] 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
Psychosis is a severe mental health problem. Symptoms of psychosis include hallucinations (e.g. hearing voices that others cannot hear) and delusions (unusual, often troubling beliefs). People who experience psychosis often have times when their symptoms are relatively stable. At other times, their symptoms may increase and become much more problematic (a 'relapse'). Helping people with psychosis to stay well (preventing relapses) is an important and time-consuming challenge for mental health services.
Smartphones and other digital technologies are now widespread. Digital technologies offer a solution to help tackle the overwhelming demand on services and to enable people with psychosis to access mental health support when they need it most (e.g. when relapsing). Research shows that people with psychosis are often willing to report their symptoms using a smartphone app. Healthcare apps can alert health professionals when someone needs extra support but can be burdensome to use long-term. We want to make a system that collects data in a timely manner, reduces the burden for both patients (by reducing the need to recall feelings) and staff and is more personalised. Recent research shows that information gathered routinely by individuals' smartphones (e.g. activity levels) might help predict relapse in long-term conditions. We want to extend our work to develop an accurate and dynamic digital remote data collection system that predicts psychosis relapse.

Who can participate?
- Adults of working age (16 years and older);
- Within the past two years have had at least one acute episode of psychosis (including relapse and first episode) leading to an unscheduled episode of acute care, including inpatient admission or acute home treatment / crisis intervention;
- Received a clinical diagnosis of schizophrenia spectrum disorder (ICD10 F20 - 29);

What does the study involve?
Participants will be asked to wear a wrist-worn device (either a Fitbit or smartwatch) and carry a smartphone for 12 months. Collection of passively collected data will provide data on potential predictors of our outcome (relapse). We will not collect information that can directly identify the

participant. Participants will also be prompted via the CONNECT app throughout the week to provide subjective information about symptoms, mood and other contextual items. The subjective report provides reliable insight into the variability of participants experiences over time. Every four months, we will ask participants to complete some questionnaires about, for example, their symptoms, mood, technology use and quality of life. At the end of the study period, participants will be given the opportunity to see and discuss the information collected about them with the research team and debrief about the study. A small number (n=60) will be asked to participate in an additional interview to find out more about their experiences of participating in the study.

What are the possible benefits and risks of participating?
Benefits:
- We hope our meetings and interviews will provide an open and comfortable space in which participants can feel free to share their thoughts, feelings, and opinions. Participants in previous studies have commented that they enjoyed the opportunity to discuss their experiences with a researcher.
- Participants may also find that being involved in research which aims to inform mental health care will empower them. The researcher will ensure that the participants are aware of how important and valued their contribution is to the study and potentially the treatment of psychosis in the future.
- The Lived Experience Advisory Panel has reported that contributing to new knowledge has the potential to transform the way in which people with lived experience of psychosis interact with services, the way in which services deliver care, and the ability to stay well in the future.
- At the end of the study, we will provide each participant with a summary of their information and provide an opportunity to talk about it with the research team. Learning more about how their sleep, thoughts and feelings, behaviours and phone usage relates to their mood and symptoms will allow opportunity for improved self-management and insight, and communication with their healthcare provider.
Risks:
- Sensitive / potentially distressing topics.
The questions the researchers will be asking in the research assessments can include sensitive and emotive distressing topics, and this may have an impact on members of our research team involved in the planned data collection activities. Research workers will have weekly supervision with a qualified member of the team, and monthly joint supervision with the project clinical team member. They can also request additional supervision with the site leads should they need support more urgently. These systems will ensure appropriate opportunities for raising, discussing and resolving any emotive or challenging issues arising from the assessments conducted as part of this study, and the implementation of steps for ensuring that all research workers will be optimally supported. The research workers will also receive appropriate training in distress management from their local Trusts and from an experienced clinician.
- Participants may find using the wearable device, or answering questions on the CONNECT app, difficult or unsettling. If they do, they will be able to discuss this with a member of our team or with an NHS professional they already know. The research team will try to help them feel at ease and remind them that they do not have to answer any questions they do not want to. They can ask the researcher to move on or stop the assessment altogether if they find any of the questions upsetting. We hope this study will help us learn how to make the app and wearable easier to use, and will ask participants about any difficulties at the end of the study.
- Some people may feel uncomfortable having some information about their sleep or location collected. We will make sure to explain exactly what data is being collected, and how we will protect the participant’s confidentiality. Participants can also contact the research team at any time if they feel unhappy about any part of the study.
- The wearables used in this research are very safe; they are commercially available devices and

have undergone extensive safety testing. There is a very small chance a participant may develop a skin rash on the part of the wrist where the wearable device is worn, in which case they can remove it. We also ask that participants do not complete the questions on the smartphone apps when in a situation where they need to pay attention, such as driving or crossing the road.
- There is a small risk that the technologies used in this study could be hacked. If this occurrs, we will immediately follow relevant procedures to fix this. However, this risk is the same as with any smartphone or commercial fitness tracker use. The encryption and data de-identification processes have been put in place to minimise any risk to the participant in the unlikely event of hacking.

Where is the study run from?
The University of Manchester (UK)

When is the study starting and how long is it expected to run for?
October 2020 to December 2027

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr Jane Lees, Project Manager
Jane.Lees@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Jane Lees

Contact details
3rd Floor Jean McFarlane Building, The University of Manchester, Oxford Road
Manchester
United Kingdom
M13 9PL
+44 (0)161 529 3834
jane.lees@manchester.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
322875

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55325, WT 222875/Z/21/Z

Study information

Scientific Title
CONNECT: Digital markers to predict psychosis relapse

Acronym
CONNECT

Study objectives
This is a prospective, observational cohort study (non-randomised, non-interventional) with an in-built process evaluation and assessment of feasibility and acceptability of wearable devices, using commercially available wearable technology and smartphone sensors, representing no change to the usual care or treatments of participants due to participation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/06/2023, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 23/WM/0044

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Psychosis

Interventions
Current interventions, as of 23/05/2025:

We aim to recruit 1100 relapse-prone individuals with a schizophrenia spectrum diagnosis. To achieve our objectives, we will recruit one cohort (data will be split into two groups):
- Group 1 (n = 800): in which we will collect data to derive and internally test a personalised relapse risk prediction algorithm using ASM items, passively collected behavioural, environmental and contextual data, integrated using machine learning (see statistical analysis section for details of the methods). We will also develop the adaptive sampling algorithm.
- Group 2 (n = 300): in which we will apply and temporally test the risk prediction algorithm and the adaptive sampling algorithm from Group 1. Note the adaptive sampling algorithm will not change the data collection in any way, nor will it be used to monitor, prevent or treat psychosis; we will simply use the data collected to test the algorithm.

This design of derivation/internal validation and subsequent temporal validation is appropriate to assess the algorithm's validity. Group 2 acts as a temporal validation set to test the prediction model and the adaptive sampling model on previously unseen individuals (recruited latest in time). A future study will examine whether our predictive and adaptive sampling algorithms can improve clinical decision-making on early intervention for psychosis relapse (but this will not be tested in the proposed study).

Nested pilot of the wearable device.
To assess the feasibility and acceptability of different types of wearable devices, we conducted a smartwatch vs Fitbit comparison nested in the main cohort study for the first 100 participants consented into the study (minimum of n = 10 at each site to represent demographic/regional characteristics at each site). These participants were offered a choice of which wearable to use, and we monitored the acceptability and data quality of the wearable device selected. Specifically, we assessed which wearable device (Fitbit, Android smartwatch, Apple Watch): do most participants choose to use; is most acceptable to participants (after using it); provides the highest quality data over a minimum of 2 months. To avoid participants carrying two phones, and to enable integration of data with compatible phones, those participants who own/use an iPhone were able to select either an Apple Watch or a Fitbit (the two wearables compatible with iOS). Those participants who own/use an Android phone were able to select either an Android smartwatch or a Fitbit (the two wearables compatible with Android). If participants already owned one of the wearable devices compatible with the DRM platform, they could continue to use that wearable device.
After six months, we assessed the quality of data collected from pilot study participants, ensuring that each had at least two months of follow-up. We also evaluated the acceptability of the devices used. To account for potential selection bias, we compared participants' baseline data across different wearables. A predefined set of parameters, outlined in our statistical analysis plan, guided our decision-making for the next steps following the six-month data collection period. These decision parameters included factors such as
• If one wearable is clearly superior, we will recommend this wearable for the remainder of the cohort.
• If there are no differences between the wearables, we will check for non-inferiority of the Fitbit compared to smartwatch against pre-defined non-inferiority bounds.
• If non-inferiority is established, we will switch to Fitbit as it is the most affordable option.
• If the data is inconclusive (i.e. not superior but also not non-inferior), we will continue to collect data for a further 6 months and repeat analysis based on the a priori parameters on all recruited participants with at least 2 months of follow-up time.

Following analysis of the pilot data, the Samsung Galaxy Watch was discontinued for the study. This decision was based on several factors: the low quantity and quality of data recorded, the significant resources required to resolve issues with data flow, and the limited metrics provided by the device. In contrast, the Fitbit was retained due to its ability to record a high volume of data, the quality and reliability of the data, and the additional metrics it offers to address the study's primary research objectives. However, the Fitbit did not demonstrate non-inferiority compared to the Apple watch. Therefore, the Apple watch was retained due to its high acceptability and uptake among participants, and the additional metrics available over and above the Fitbit in meeting the study's research objectives. As this is a nested study, the dataset gathered from pilot participants will form part of the main cohort dataset

Procedure.
Participants will be asked to wear a wrist-worn device (either a Fitbit or smartwatch) for the study period, during which longitudinal heart rate, accelerometery data, for example, will be

prospectively collected. During the same period, standard in-built smartphone sensors will collect for example data on call activity (not the content of calls), (obfuscated rather than exact) location, physical activity, sleep, battery life, light levels. Collection of passively collected data over the 12 month study period will provide data on potential predictors of our outcome (relapse). Participants will also be prompted via the CONNECT app throughout the week to provide subjective information (rated on a Likert scale using a simple slider scale in the app) about symptoms, mood and other contextual items. The subjective report provides reliable insight into the variability of participants experiences over time.

_____

Previous interventions:

We aim to recruit 1100 relapse-prone individuals with a schizophrenia spectrum diagnosis. To achieve our objectives, we will recruit one cohort (data will be split into two groups):
- Group 1 (n = 800): in which we will collect data to derive and internally test a personalised relapse risk prediction algorithm using ASM items, passively collected behavioural, environmental and contextual data, integrated using machine learning (see statistical analysis section for details of the methods). We will also develop the adaptive sampling algorithm.
- Group 2 (n = 300): in which we will apply and temporally test the risk prediction algorithm and the adaptive sampling algorithm from Group 1. Note the adaptive sampling algorithm will not change the data collection in any way, nor will it be used to monitor, prevent or treat psychosis; we will simply use the data collected to test the algorithm.

This design of derivation/internal validation and subsequent temporal validation is appropriate to assess the algorithm's validity. Group 2 acts as a temporal validation set to test the prediction model and the adaptive sampling model on previously unseen individuals (recruited latest in time). A future study will examine whether our predictive and adaptive sampling algorithms can improve clinical decision-making on early intervention for psychosis relapse (but this will not be tested in the proposed study).

Nested pilot of the wearable device.
To assess the feasibility and acceptability of different types of wearable devices, we will conduct a smartwatch vs Fitbit comparison nested in the main cohort study for the first 100 participants consented into the study (minimum of n = 10 at each site to represent demographic/regional characteristics at each site). These participants will be offered a choice of which wearable to use, and we will monitor the acceptability and data quality of the wearable device selected. Specifically, we will assess which wearable device (Fitbit, Android smartwatch, Apple Watch): do most participants choose to use; is most acceptable to participants (after using it); provides the highest quality data over a minimum of 2 months. To avoid participants carrying two phones, and to enable integration of data with compatible phones, those participants who own/use an iPhone can select either an Apple Watch or a Fitbit (the two wearables compatible with iOS). Those participants who own/use an Android phone can select either an Android smartwatch or a Fitbit (the two wearables compatible with Android). If participants already own one of the wearable devices compatible with the DRM platform, they can continue to use that wearable device.
After 6 months, we will review the quality of data collected from these 100 participants (with a minimum of 2 months of follow-up time for the last recruited participant) and acceptability of the device used. We will compare the participants' baseline data for differences between wearables to ensure any selection bias is accounted for. We will define a set of a priori parameters written into our statistical analysis plan on which to base a decision about how we proceed after

the 6-month data collection period. For example, after accounting for selection factors:
- If one wearable is clearly superior, we will recommend this wearable for the remainder of the cohort.
- If there are no differences between the wearables, we will check for non-inferiority of the Fitbit compared to smartwatch against pre-defined non-inferiority bounds.
- If non-inferiority is established, we will switch to Fitbit as it is the most affordable option.
- If the data is inconclusive (i.e. not superior but also not non-inferior), we will continue to collect data for a further 6 months and repeat analysis based on the a priori parameters on all recruited participants with at least 2 months of follow-up time.

If the parameters are not met, we will continue with data collection for a further 6 months and review data quality and acceptability according to the same set of parameters used at 6 months. As this is a nested study, the dataset gathered from these 100 participants will form part of the main cohort dataset.

Procedure.
Participants will be asked to wear a wrist-worn device (either a Fitbit or smartwatch) for the study period, during which longitudinal heart rate, accelerometery data, for example, will be prospectively collected. During the same period, standard in-built smartphone sensors will collect for example data on call activity (not the content of calls), (obfuscated rather than exact) location, physical activity, sleep, battery life, light levels. Collection of passively collected data over the 12 month study period will provide data on potential predictors of our outcome (relapse). Participants will also be prompted via the CONNECT app throughout the week to provide subjective information (rated on a Likert scale using a simple slider scale in the app) about symptoms, mood and other contextual items. The subjective report provides reliable insight into the variability of participants experiences over time.

Intervention Type
Other

Primary outcome(s)
Current primary outcome as of 30/12/2025:
Relapse within 12 months of entering the study measured using patient records defined as:
1. A return or exacerbation in psychotic symptoms of at least moderate degree OR,
2. A return or exacerbation of cognition / disorganisation of at least a moderate degree, AND,
3. Where symptoms have lasted at least one week in duration AND,
4. Where there is evidence of a decline in functioning OR an increase in risk to self or others AND,
5. There is evidence of an escalating clinical response from services.

Previous primary outcome:
Relapse within 12 months of entering the study measured using patient records defined as:
1. A return or exacerbation in psychotic symptoms of at least moderate degree OR,
2. A return or exacerbation of affective symptoms of at least a moderate degree, OR,
3. A return or exacerbation of cognition / disorganisation of at least a moderate degree, OR,
4. A return or exacerbation of excitement of at least a moderate degree, AND
5. Where symptoms have lasted at least one week in duration AND,
6. Where there is evidence of a decline in functioning OR an increase in risk to self or others AND,
7. There is evidence of an escalating clinical response from services.

Key secondary outcome(s))
Current secondary outcome measures as of 23/05/2025:

Measured at baseline, 4, 8 and 12 months:
1. Mental Health Status - Clinical Global Impression-Schizophrenia scale and Psychotic Symptom Rating Scales (PSYRATS) distress and frequency scale
2. Emotional Distress - Calgary Depression Scale, Fear of Recurrence Scale, Work and Social Adjustment Scale, Criticism and Warmth Scale, Dunn Worry Questionnaire, General Anxiety Disorder Questionnaire, EQ-5D-5L
3. Substance misuse - Alcohol, Smoking and Substance Involvement Screening Test – LITE (ASSIST-LITE)
4. Service use & clinical relapse - Captured from the medical record, Medication Adherence Rating scale
5. Technology use - Self-reported acceptability and usability using Post-Study System Usability Questionnaire (measured at 4, 8 and 12 months only)

Previous secondary outcome measures:

Measured at baseline, 3, 6, 9 and 12 months:
1. Mental Health Status - Clinical Global Impression-Schizophrenia scale and Psychotic Symptom Rating Scales (PSYRATS) distress and frequency scale
2. Emotional Distress - Calgary Depression Scale, Fear of Recurrence Scale, Work and Social Adjustment Scale, Criticism and Warmth Scale, Dunn Worry Questionnaire, General Anxiety Disorder Questionnaire, EQ-5D-5L
3. Substance misuse - Alcohol, Smoking and Substance Involvement Screening Test – LITE (ASSIST-LITE)
4. Service use & clinical relapse - Captured from the medical record, Medication Adherence Rating scale
5. Technology use - Self-reported acceptability and usability using Post-Study System Usability Questionnaire (measured at 3, 6, 9 and 12 months only)

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 23/05/2025:

Participants will be people with lived experience of psychosis on existing caseloads of secondary care mental health teams in NHS Trusts/Health Boards who are:
1. Adults of working age (16+ years)
2. Within the past 2 years have had at least one acute episode of psychosis (including relapse and first episode) leading to an unscheduled episode of acute care, including inpatient admission or acute home treatment/crisis intervention
3. Received a clinical diagnosis of, or confirmed by the treating clinician to meet the criteria of, schizophrenia spectrum disorder (ICD10 F20 - 29)
4. Current presentation does not include severe acute symptoms
5. In accordance with the Mental Capacity Act, mental capacity will be assumed. If there is any doubt, then a capacity assessment will be carried out by a clinician from the study team or the responsible clinician

———

Previous inclusion criteria:

Participants will be people with lived experience of psychosis on existing caseloads of secondary care mental health teams in NHS Trusts/Health Boards who are:
1. Adults of working age (16+ years)
2. Within the past 2 years have had at least one acute episode of psychosis (including relapse and first episode) leading to an unscheduled episode of acute care, including inpatient admission or acute home treatment/crisis intervention
3. Received a clinical diagnosis of schizophrenia spectrum disorder (ICD10 F20 - 29)
4. Current presentation does not include severe acute symptoms
5. In accordance with the Mental Capacity Act, mental capacity will be assumed. If there is any doubt, then a capacity assessment will be carried out by a clinician from the study team or the responsible clinician

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current exclusion criteria as of 23/05/2025:

1. Experienced a recent relapse within the previous 12 weeks as confirmed by the treating clinician
2. Non-English speaking

———

Previous exclusion criteria:

1. Experienced a recent relapse, operationally defined as having been discharged from the care of a crisis team/psychiatric inpatient service within the previous 12 weeks
2. Non-English speaking

Date of first enrolment
01/03/2024

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

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

Study participating centre
South London and Maudsley NHS Foundation Trust
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
England
BR3 3BX

Study participating centre

Cardiff & Vale University UHB
Woodland House
Maes-y-coed Road
Cardiff
Wales
CF14 4HH

Study participating centre
Aneurin Bevan University UHB
Headquarters - St Cadoc's Hospital
Lodge Road
Caerleon
Newport
Wales
NP18 3XQ

Study participating centre
Cwm Taf Morgannwg University Local Health Board
Dewi Sant Hospital
Albert Road
Pontypridd
Wales
CF37 1LB

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
England
BN13 3EP

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
Scotland
G12 0XH

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

Study participating centre
University of Manchester
Jean McFarlane Building (3rd Floor), Oxford Road
Manchester
England
M13 9PL

Study participating centre
University of Edinburgh
Medical Quad
Teviot Place
Edinburgh
Scotland
EH8 9AG

Study participating centre
University of Glasgow
Mental Health Research Facility
Fleming Pavilion, West of Scotland Science Park (Todd Campus)
Glasgow
Scotland
G20 0XA

Study participating centre
Cardiff University
Haydn Ellis Building
Maindy Rd
Cardiff
Wales
CF24 4HQ

Study participating centre

University of Sussex
Falmer
Brighton
England
BN1 9RP

Study participating centre
King's College London
Institute of Psychology, Psychiatry and Neuroscience, KCL
Henry Wellcome Building
London
England
SE5 8AF

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research organisation

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Direct access will be granted to authorised representatives of the Sponsor, funder and the health authorities to examine deidentified records, to satisfy quality assurance reviews, audits and evaluations of study safety and progress. To add benefit and impact, the data we collect will also be a valuable scientific resource as a platform for downstream research into psychosis, given the breadth, depth, and resolution of the data we will collect. We will ensure that the data can be reused for secondary analysis by publishing schemas and data dictionaries. An anonymised dataset will be created and archived at the University of Manchester. This data will be made available on application to researchers for non-commercial research. Request for data will be subject to approval by a Data Access Committee.
The main dataset that the research will generate will be the de-identified data from ASM, Passive monitoring, clinical assessments, and demographic information. We will obtain consent from participants to share this data with other researchers for secondary analysis in future related research studies (including student research projects), ensuring that participants are fully informed of this before consenting. The de-identified dataset will be securely stored on the University of Manchester Research Data Management System (RDMS) for up to 20 years and then destroyed.
Researchers involved in the study will have direct access to the dataset during the study for the purposes of preparing study reports and publications. Researchers involved in the study who wish to use the data for secondary analysis will be required to make a formal request to the Project Management Group, overseen by the Project Board, including completing a research study proforma detailing the specific research question they wish to address. Researchers external to the study (including student researchers) may also request access to the dataset for secondary analysis via the same route. In all cases, access to the dataset will follow the terms of the funding agreement and proposals for add-on studies must lie within the scope of the aims and objectives of the CONNECT study.
Requests for access should be submitted to Sandra.Bucci@manchester.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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