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A multicentre trial to assess the validity of the Kardia six-lead hand-held ECG in psychiatry

Submission date
29/12/2025

Recruitment status
Recruiting

Registration date
02/02/2026

Overall study status
Ongoing

Last Edited
02/02/2026

Condition category
Circulatory System

[ ] 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
Some medications that are prescribed for patients with mental health problems have side effects that can affect the heart. Doctors use heart tracings called ECGs to understand how the heart is working and ensure it is safe for the person to take these medications. To have a standard ECG, electrode stickers are stuck on the person's chest, wrists and ankles, who then needs to lie still whilst the ECG is recorded. Sometimes, people who need an ECG cannot have it. For example, people who are in distress may not be able to undress or lie still. Sometimes people feel uncomfortable undressing in front of others. Often, NHS clinics do not have the facilities to do ECGs, and the person's GP is asked to do it. Our work has shown that this causes delays in treatment and extra appointments.
A new credit-card-sized ECG device (the Kardia 6L [K6L]) has recently been developed. To use it, the person rests two fingers on top of the device and places it so that the back touches the skin of their knee or ankle. The recordings are sent to a phone via Bluetooth. We think the K6L will help more people with mental illness get the ECGs they need. This would help improve safety for people taking medication, reduce the number of appointments and improve the experience for people. We have already shown that the K6L works well in patients seen in a cardiology service. We want to find out how well it works in people seen in mental health services.

Who can participate?
Patients aged 18 years and over who have been prescribed an antipsychotic medication in any setting

What does the study involve?
Once consented into the study, participants will first have their demographic information and relevant history recorded. This will be done by reviewing the patient records (notes) and speaking to the participant. Every participant will have their height and weight recorded. Participants will have a 12L ECG followed by a 6L ECG. The 6L should be started as soon as possible after the 12L ECG has been recorded. This time should be no longer than 2 minutes after the 12L has been recorded. The operator will be either a research assistant or a research nurse. At selected sites, a healthcare worker from the participant’s regular clinical team who has been trained to conduct ECGs will carry out the ECGs. The operator of the machines will record the time taken to conduct the 12L from the point that the participant starts to undress or the

operator starts to prepare the equipment (whichever comes first). The operator will record the time taken to conduct a 6L starting from the time the operator starts to prepare the equipment. After the ECGs have been take the operator will ask the participant a two-question survey: If you were to have this procedure again with either machine, which test would you choose? What are the reasons you chose [answer from question 1]?

What are the possible benefits and risks of participating?
We do not anticipate any adverse events in this study. No intervention is being delivered, and data is being collected at one timepoint.

Where is the study run from?
Leeds Yorkshire Partnership Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2026 to April 2027

Who is funding the study?
Alivecor, Inc. (USA)

Who is the main contact?
1. Nazya Azam, nazya.azam@nhs.net
2. Dr George Crowther, georgecrowther@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

Central Portfolio Management System (CPMS)
61500

Integrated Research Application System (IRAS)
356658

Study information

Scientific Title
A multicEntre trial to AssesS the validitY of the Kardia six-lead hand-held ECG in psychiatry (Easy ECG V1)

Acronym
Easy ECG V1

Study objectives
1. Compare the diagnostic accuracy of the K6L to the 12L for QT interval in people taking antipsychotic medication.
2. Compare the time to obtain QTc readings between the K6L and 12L – efficiency.
3. Understand the patient acceptability of the K6L compared with the 12L.
4. Using the NICE EVA as reference, determine why and how frequently it is necessary to perform a 12L after a K6L.
5. Describe the prevalence of QT prolongation in patients taking antipsychotics.
6. Understand the clinician acceptability of the K6L.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/10/2025, HRA and Health and Care Research Wales (HCRW) (2 Redman Place, Stratford, London, E20 1JQ, UK; Tel: not available; approvals@hra.nhs.uk), ref: 25/YH/0173

Study design
Non-randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular and mental health

Interventions

We will conduct a multi-centre study comparing K6L vs 12L ECGs in people receiving antipsychotic therapy. There will be ten NHS sites in total. Our sites span England and Wales and serve a range of rural, urban and semi-rural communities. This will allow us to ensure participants are from a wide range of socioeconomic and ethnic backgrounds. Duration is eighteen months in total (3 months set up, 12 months data collection, 3 months analysis and write up). Recruitment will take place in any clinical area where antipsychotic treatments are prescribed (outpatient or inpatient) in eligible people.

Study procedures consist of one 12L ECG and one KardiaMobile 6L ECG per participant, recorded sequentially by the same individual. The 6L should be started as soon as possible after the 12L ECG has been recorded. This time should be no longer than 2 minutes after the 12L has been recorded.

Once consented into the study, participants will first have their demographic information and relevant history recorded. This will be done by reviewing the patient records (notes) and speaking to the participant.

Demographic information:
1. Age
2. Gender at birth
3. Ethnicity
4. Height
5. Weight

History:
1. Primary psychiatric diagnosis for which the antipsychotic is prescribed for
2. Other psychiatric diagnoses
3. Current antipsychotic treatment – type/types of antipsychotic, dose and administration route
4. Other prescribed medications that can impact QT interval
5. Cardiovascular history

The 12L will be collected using a MAC 550 (GE Healthcare, WI, USA) or equivalent recorder (calibrated as per machine standards). The 6L will be collected using an Alivecor Kardiamobile 6-lead ECG machine.
The operator will be either a research assistant or research nurse. At selected sites (Leeds, Hull, Tees Esk and Wear Valleys (TEWV) and Kent), a healthcare worker from the participant's regular clinical team who has been trained to conduct ECGs will carry out the ECGs.
The operator of the machines will record the time taken to conduct the 12L from the point that the participant starts to undress or the operator starts to prepare the equipment (whichever comes first). The operator will also record the time taken to conduct a 6L starting from the time the operator starts to prepare the equipment.
After the ECGs have been take the operator will ask the participant a two-question survey:
1. If you were to have this procedure again with either machine, which test would you choose?
2. What are the reasons you chose the [answer from question 1]?
Participant survey data will be analysed to understand patient acceptability. A simple count will be used to demonstrate preference between the devices (survey question 1). Content analysis will be used to illustrate the reasons behind this decision and a list of the top 5 reasons for the preference will be created for each type of machine.

Healthcare worker time to treatment and ECG quality analysis:
At selected sites (Leeds, Kent, Hull and TEWV), 80 ECGs will be collected by a member of the

participant's usual treating team who has been trained to use K6L and 12L ECGs. This is to test whether there is a difference in time taken to complete the ECGs and the K6L ECG quality when ECGs are completed by a researcher compared to the usual treating team (real world setting). The data recorded will be identical to the data collection set out above, except that the person conducting the ECG will be asked to indicate which ECG they prefer and why (objective 6).
The ECGs will be graded by independent observers who are blinded to the patient and patient details. Noise on ECG will be described according to a noise score (NS) where NS 1 is a completely clear ECG, NS 2 is an ECG with noise but where a good interpretation was possible, NS 3 borderline ECG for noise (analysis based on RR regularity), and NS 4 is not interpretable.

K6L validation:
The automated QT and QTc analysis will be recorded. This data will be available to the clinical team to aid patient management. Additionally, all other automated intervals will be recorded, e. g. PR interval.
Statistical analysis will be performed (Bland Altman and regression analysis) to compare the differences in these results between the 12L versus the K6L for QT, QTc and PR intervals in leads I, II, and AvL. Equivalence of the measurements using the two methods will be carried out using standard equivalence testing methods at a 5% level of significance, with 95% limits of agreement reported.

Time to obtain ECG reading:
Statistical analysis will be performed to compare the time taken to complete the 6- and 12-lead ECGs. Two separate analyses will be reported:
1. The difference in time when the ECGs are performed by a research assistant.
2. The difference in time when the ECGs are performed by a member of the clinical team (who has been trained to conduct ECGs).

Frequency of the need to repeat ECG following K6L:
From the 6L data only, using the NICE early valuation assessment criteria for when a repeat QT interval measurement using a 12-lead electrocardiogram (ECG) device is offered following a 6-lead ECG*, we will report the number and proportion of times it would be necessary to complete a 12 Lead ECG following a 6-lead ECG.
*When QTc interval is > 440 in men or >470 in women.

Prevalence of QT prolongation:
The whole cohort will be used to demonstrate the prevalence of QT prolongation in (>440 in men, >470 in women) in people taking antipsychotics. We will also use the data to demonstrate any dose-related effects of antipsychotics on QT (total daily antipsychotic dose as an equivalent to haloperidol vs QTc), and any differences in QTc dependant on antipsychotic type or administration route. All prevalence data will be displayed as a percentage.

Recruitment:
Potential participants will be identified by their clinical care team, in conjunction with local site research assistants or research nurse (depending on site preference). A research assistant or research nurse (depending on site preference) at each site will recruit 80 participants from both wards and outpatient clinics. The research assistant/nurse will provide the participant information sheet and explain the study. We will work with our PPI group to ensure these materials are understandable and provide easy read versions. Furthermore, we have budgeted for services to translate patient information where necessary.
It is hoped that participants will be recruited on the same day, but where necessary they will be given time to consider participation or discuss it with family and friends. Where potential participants lack capacity to consent, personal consultees will be approached on their behalf.

Patients who do not wish to participate will receive treatment as usual.

ECG registry:
Every recruited patient will have the opportunity to opt into a long-term registry. Consent will be obtained to enable the study team to collect adverse cardiac event data and details of the psychotropic prescriptions from hospital or GP records for 10 years.

Intervention Type
Other

Primary outcome(s)
1. QT interval measured using Kardia 6L and standard 12-lead ECG at baseline

Key secondary outcome(s))

Completion date
01/04/2027

Eligibility

Key inclusion criteria
Any patient prescribed or due to be prescribed an antipsychotic medication in any setting (ward or outpatient)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Aged under 18 years old
2. Patients who lack capacity and do not have a personal consultee to give advice or where the personal consultee does not think they would want to take part

Date of first enrolment
04/12/2025

Date of final enrolment
01/04/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds and York Partnership NHS Foundation Trust
St. Marys House
St. Marys Road
Leeds
England
LS7 3JX

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
Kent and Medway Mental Health NHS Trust
Farm Villa
Hermitage Lane
Maidstone
England
ME16 9PH

Study participating centre
Essex Partnership University NHS Foundation Trust
The Lodge
Lodge Approach
Runwell
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SS11 7XX

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq Block a Willerby Hill
Beverley Road
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HU10 6ED

Study participating centre
Bradford District Care NHS Foundation Trust
New Mill
Victoria Road
Saltaire
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BD18 3LD

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House
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CB21 5EF

Study participating centre
Surrey and Borders Partnership NHS Foundation Trust
18 Mole Business Park
Randalls Road
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KT22 7AD

Study participating centre
Hampshire and Isle of Wight Healthcare NHS Foundation Trust
Tatchbury Mount Hospital
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SO40 2RZ

Sponsor information

Organisation
Leeds and York Partnership NHS Foundation Trust

ROR
https://ror.org/00n635c12

Funder(s)

Funder type
Government

Funder Name
Alivecor, Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date