This protocol has regard for the HRA guidance and order of content

FULL/LONG TITLE OF THE STUDY
A feasibility study using movement and perspective-taking as a diagnostic aid for psychosis

SHORT STUDY TITLE / ACRONYM
Movement and perspective-taking as a diagnostic aid for psychosis

PROTOCOL VERSION NUMBER AND DATE
Version 1.0, 01 February 2018

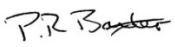
RESEARCH REFERENCE NUMBERS

IRAS Number:	236262
SPONSORS Number:	1718/26
FUNDERS Number:	N/A

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Principal Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor
I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:
Signature: Date: 01/02/2018



Name (please print): Ms Pam Baxter

Position: Senior Research Governance Officer

Principal Investigator:
Signature: Date: 01/02/2018

Name: (please print): Krasimira Tsaneva-Atanasova

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KEY STUDY CONTACTS

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Co-Principal Investigator	Dr Sarah Sullivan University of Bristol, School of Social and Community Medicine, BF11, Oakfield House, Oakfield Grove, BS8 2BN, Bristol sarah.sullivan@bristol.ac.uk 0117 331 4029
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Sponsor	University of Exeter Sponsor Representative Ms Pam Baxter Senior Research Governance Officer Research Ethics and Governance Office Lafrowda House, St Germans Road, Exeter EX4 6TL
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	EPSRC Impact Acceleration Account Research Capability Funding - Avon and Wilshire Mental Health Partnership NHS Trust Seed Corn funding – Jean Golding Institute, University of Bristol
Key Protocol Contributors	Prof Krasimira Tsaneva-Atanasova University of Exeter, Department of Mathematics, College of Engineering, Mathematics and Physical Sciences, Living Systems Institute, Stocker Road, EX4 4QD, Exeter k.tsaneva-atanasova@exeter.ac.uk Dr Sarah Sullivan University of Bristol, School of Social and Community Medicine, BF11, Oakfield House, Oakfield Grove, BS8 2BN, Bristol sarah.sullivan@bristol.ac.uk Dr Piotr Słowiński University of Exeter, Department of Mathematics, College of Engineering, Mathematics and Physical Sciences, Living Systems Institute, Stocker Road, EX4 4QD, Exeter p.m.slowinski@exeter.ac.uk Dr Anke Karl University of Exeter, Department of Psychology, College of Live and Environmental Sciences a.karl@exeter.ac.uk Ms Rosemary Greenwood, University Hospitals Bristol NHS Foundation Trust, Level 3 Education Centre, Upper Maudlin Street, BS2 8AE, Bristol rosemary.greenwood@UHBristol.nhs.uk, 0117 34 20234 Mr Bradley Jones

	Avon & Wilts Mental Health Partnership NHS Trust, Bristol Early Intervention Team, Colston Fort, BS6 5UB, Bristol bradleyjones@nhs.net 0117 919 2371
Committees	N/A

STUDY SUMMARY

Study Title	A feasibility study using movement and perspective-taking as a diagnostic aid for psychosis
Internal ref. no. (or short title)	Movement and perspective-taking as a diagnostic aid for psychosis
Study Design	Feasibility study
Study Participants	People accepted for an assessment for psychosis or risk of developing psychosis and people with first episode psychosis or being at risk of developing psychosis
Planned Size of Sample (if applicable)	100 service users and 50 controls
Follow up duration (if applicable)	N/A
Planned Study Period	1/3/18 - 31/8/18
Research Question/Aim(s)	1/ We want to investigate accuracy of classifiers based on movement and coordination during an interaction with a computer avatar in people who are considered at risk of psychosis or who have a newly diagnosed psychotic disorder, compared to healthy controls and those who do not have psychosis or a future risk of psychosis. 2/ We want to investigate feasibility of this diagnostic procedure in a clinical setting and gather opinions about the task and the interface from the service users and clinicians.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Emma Roberts, University of Exeter, INNOVATION, IMPACT & BUSINESS, The Innovation Centre, Rennes Drive, Exeter, EX4 4RN EPSRC-IAA@exeter.ac.uk	**£30,507 (EPSRC Impact Acceleration Account)**
Dr Julian Walker Avon and Wilshire Mental Health Partnership NHS Trust, Fromeside, Blackberry Hill Hospital, Manor Road, BS16 2EW, Bristol julian.walker@nhs.net 0117 378 4267	**£4137 (RCF 17-18-008), access to Early Intervention Teams, mental health expertise**
Patricia Holley Jean Golding Institute, Royal Fort House, University of Bristol, BS8 1UH, P.Holley@bristol.ac.uk	**£3,249 (JGI seed corn)**
Tobit Emmens, Devon Partnership NHS Trust, Honorary Senior Research Fellow, University of Exeter Medical School, Wonford House, Exeter, EX2 5AF +44(0)1392 674114	**access to Early Intervention Teams, mental health expertise**

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor of this multi-site study is University of Exeter

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering group
Prof Krasimira Tsaneva-Atanasova – professor of mathematics for healthcare, University of Exeter. Principal applicant for the EPSRC Impact acceleration account. Co-applicant for the RCF 17-18-008 funding. Principal investigator. Supervision of data collection and analysis; co-developed the proposed diagnostic methodology.

Dr Sarah Sullivan – research fellow, University of Bristol. Main applicant for the RCF 17-18-008 funding. Lead applicant for the Jean Golding Institute seed corn funding. Co-principal investigator.

Dr Piotr Słowiński – research fellow, University of Exeter. Co-applicant for the EPSRC Impact acceleration account. Co-applicant for the Jean Golding Institute seed corn funding. Study coordinator. Data collection and analysis. Co-developed the proposed diagnostic methodology.

Dr Anke Karl - senior lecturer, University of Exeter. Co-applicant for the EPSRC Impact acceleration account. Clinical psychology.

Mr Bradley Jones – peer support worker, AWP NHS Trust. Co-applicant for the RCF 17-18-008 funding. PPI coordinator

Mr Tobit Emmens – the Managing Partner, Research & Development, DP NHS Trust. DPT representative.

Dr Julian Walker – research and development director for AWP NHS trust. AWP representative.

Ms Rosemary Greenwood – senior statistician, Research Design Service – South West. Research design advice.

Patient & Public Involvement
The study steering group will also collaborate closely with the Psychosis Health Integration Team (HIT) in Bristol on aspects of study design, acceptability, planning and dissemination activities.

The Psychosis HIT is a multidisciplinary group of academics, clinicians, commissioners, patients, carers and third sector health providers who have a common aim of improving services and outcomes for people with psychosis in the Bristol area. There are 7 work-streams one of which is improving care pathways, which fits well with our study plan. The Psychosis HIT is led by one of the applicants, a consultant psychiatrist (Dr Simon Downer), the chair of Bristol Clinical Commissioning Group (Dr Martin Jones) and two young people with lived experience of psychosis (Ms Martha Sneyd and Mr James Robinson). An important part of this group is the service user (i.e. patient) forum which is run by Martha and James. This group will provide an ideal platform for helping us to develop and disseminate our ideas.

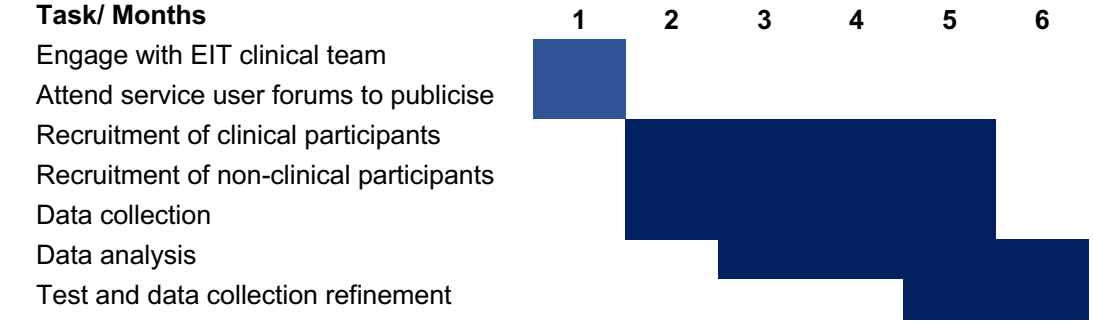
PROTOCOL CONTRIBUTORS
The sponsor and the funders do not have control over any final decision regarding any of the aspects of the study.

Final decisions concerning study design, conduct, data analysis and interpretation, and dissemination of results will be made by the Study Steering Group.

Every member of the Study Steering Group contributed to the protocol within area of its expertise.

KEY WORDS: psychosis, diagnosis, perspective-taking, movement

STUDY FLOW CHART



STUDY PROTOCOL
A cross-sectional feasibility study of using movement and perspective-taking as a diagnostic aid for psychosis

1 BACKGROUND

Psychosis defines a category of serious and long-term mental disorders, e.g. schizophrenia, characterised by loss of contact with reality and symptoms such as hallucinations, delusions and thought disorder. It is not rare, with a lifetime prevalence of 3.5% [Perala et al 2008]. Psychosis is extremely expensive to treat [Mangalore & Knapp 2006] and one of the leading causes of disability worldwide [GBoDS 2013]. Mean age of onset is 22 years for men and 26 years for women. Developing psychosis in young adulthood is devastating and disrupts the trajectory into independent adulthood. Once disrupted it is difficult to regain, leading to unfulfilled ambitions in employment, education and personal relationships and social marginalisation and isolation. Unfortunately, poor clinical and social outcomes are the norm with reports of relapse rates of 36% in the two years following recovery [Addington et al 2007] and employment of only 20% [Burns et al 2007]. Most risk factors for a poor outcome, such as gender or low socio-economic status, are difficult or impossible to modify. However, there is evidence that early treatment, facilitated by early detection, is associated with better outcomes [Marshall et al 2004].

Determining who is at greater risk is difficult. Currently, patients considered at risk are referred for further assessment by Early Intervention Teams (EITs) using a psychometric tool recommended by NICE, the Comprehensive Assessment of At Risk Mental State (CAARMS) [Yung et al 2005]. The predictive validity of the CAARMS is low. The transition rates in those defined as ARMS have been reported as 35% over 3 years in a recent meta-analysis [Fusar-Poli et al 2015], demonstrating that up to 65% of those classified as ARMS are false positives (i.e. do not go on to develop psychosis). To date, there is no evidence to support a more accurate way of making this assessment [Yung et al 2005, Fusar-Poli et al 2015].

2 RATIONALE

We want to investigate accuracy of classification based on movement and coordination during an interaction with a computer avatar for people who are considered at risk of psychosis or who have a newly diagnosed psychotic disorder, compared to healthy controls or those who are assessed as not having psychosis or a future risk of psychosis.

Accurate detection of those at risk of developing psychosis is important since duration of untreated psychosis is associated with poorer outcomes [Marshall et al 2004]. The diagnostic tool that we are proposing to test, based on assessment of non-verbal synchrony, may be a useful way of improving the accuracy of the CAARMS when detecting ARMS (i.e. it may reduce the number of false positive detections of the ARMS). More accurate detection of those at risk of psychosis will ensure that services are directed appropriately and will reduce duration of untreated psychosis.

3 THEORETICAL FRAMEWORK

Poor social functioning is a core deficit of psychosis [Burns et al 2007]. Evidence from longitudinal studies demonstrate that problems exist prior to the development of the disorder [Welham et al 2009] and in newly diagnosed patients [Sullivan et al 2013], suggesting that this deficit may be useful for prediction and understanding of aetiology. However, reliable and valid tests of social functioning and social cognition do not exist. Most rely on general cognitive ability, literacy or an understanding of social context and are affected by investigator bias and measure reflective/self-reported rather than on-line social cognitive ability. In contrast, we propose a new, objective, and data driven method to assess non-verbal synchrony, which is a core component of social functioning and social cognition. Our approach is based on a set of socio-motor biomarkers measured during the mirror task, a joint-action task, where the participant mirrors the movement of a computer avatar. Work carried out in our group reports [Slowinski et al 2017] that such biomarkers can accurately discriminate between patients with chronic schizophrenia and controls. These findings suggest that this method may be useful for detecting early psychosis or predicting which patients are more likely to develop it.

At present, we are not able to determine whether any difference is related to long-term illness or medication side effects. In this application, we propose a feasibility study to assess accuracy of the classifiers based on the mirror task performance in those who are at risk of psychosis or in their first episode because this group will be unmedicated or are only taking low doses of medication over a short period of time. We will use the classifiers to differentiate between the clinical group, a group of healthy participants of a similar age and a group of people who are assessed as not having psychosis or a future risk of psychosis.

4 RESEARCH QUESTION/AIM(S)

The aim of the study is to assess accuracy of the classification based on the mirror task performance in people who are considered at risk of psychosis or who have a newly diagnosed psychotic disorder, compared to healthy controls or those who are assessed as not having psychosis or a future risk of psychosis.

4.1 Objectives

1/ Investigate accuracy of classification based on the mirror task performance for differentiating between people who are considered at risk of psychosis or who have a newly diagnosed psychotic disorder, compared to healthy controls and those who are assessed as not having psychosis or a future risk of psychosis.
2/ Investigate whether it is feasible to use the mirror task in a routine clinical setting,
3/ Gather opinions about the mirror task and the computer avatar from the service users.

4.2 Outcome

Accurate differentiation between the groups would lead to better and more accurate healthcare technologies for diagnosis of psychosis, which would be of value to service users and the NHS.

Early and accurate detection of those at risk of developing psychosis is important since duration of untreated psychosis is associated with poorer outcomes. Precise point of care diagnostics will reduce the number of false positives ARMS cases resulting from currently used psychometric diagnostic methods (only 35% of people with ARMS will develop psychosis over the following 3 years [Fusar-Poli et al 2015]).

There are several potential beneficial outcomes resulting from this work:
1/ Service users should receive an accurate prediction of risk earlier;
2/ NHS resources and services are used more efficiently and are targeted at those most in need;
3/ The unintended harms resulting from inaccurate assessments of risk will be reduced

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Study design:

A cross-sectional feasibility study in a group of service users accepted for an assessment for psychosis or risk of developing psychosis including people with first episode psychosis (FEP) or assessed as being at risk of psychosis (ARMS).

Study procedure

1/ At the beginning of every week a team researcher will contact the clinical team manager to identify potential participants who meet inclusion criteria and to obtain dates of the Comprehensive Assessment of At Risk Mental State (CAARMS). On the day of the CAARMS a member of the study research team will contact the Early Intervention Team to remind about request for consent to contact.

2/ At the CAARMS appointment an eligible service user will be advised about the study by the clinical team, receive the written information sheet and be asked if a member of the study research team can contact them to discuss further.

3/ If the eligible service user expresses interest in the study and consent to contact is obtained, a team researcher will contact the potential participant to arrange an informed consent appointment and the research session at the NHS site. If possible, conditionally on obtaining the informed consent, the research session will follow the informed consent appointment. Otherwise the research session will take place at a separate appointment after obtaining the informed consent.

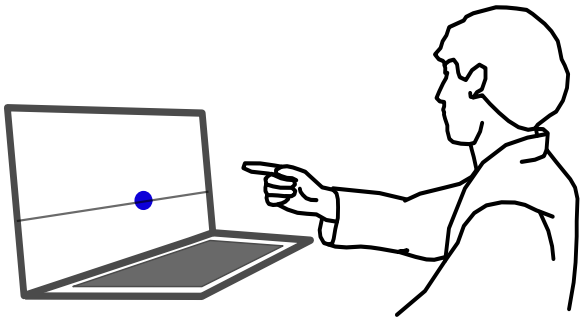
4/ Data analysis will be performed remotely (at a university) after data collection. The research session will take part at a different day and after the CAARMS; it will not influence the CAARMS assessment.

Research session:

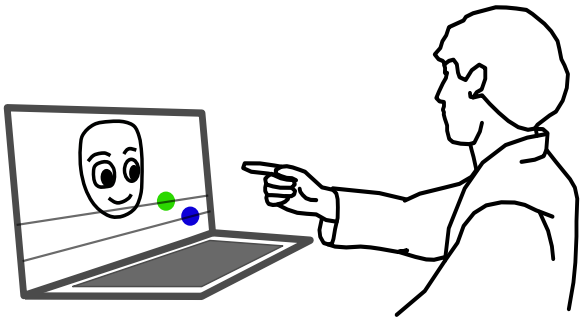
The mirror-task activity design follows our proof-of-concept studies [Slowinski et al 2016, 2017]. The game-like activity uses off-the-shelf technology consisting of a laptop computer and a movement detector (both with the CE safety mark). The participant will be asked to mirror the movements of a computer avatar on the laptop screen. The avatar uses proprietary algorithms to adapt its movements in accordance with the participant performance.

The test, therefore, measures both social movement and perspective-taking ability. The responses of the participant will be recorded using an established and tested data collection platform [Slowinski et al 2016]. The procedure is quick and non-invasive. We also think it will appeal to younger service users (those who have FEP are likely to be in their early to mid-twenties).

MAKE YOUR OWN MOVEMENT



FOLLOW MOVEMENT OF THE AVATAR



The research session will have following stages:

1.) Time for questions.
2.) 1st round of the interaction with the computer avatar (see figure above):
    a. one recording (1 minute) of participant's own movement. We will ask the participant: “Please create interesting motions and enjoy playing.”
    b. three recordings (1 minute each) of the participant following the virtual avatar. We will ask the participant: “Please try to follow the movement on the screen as accurately as you can and enjoy playing.”
    c. one recording (1 minute each) of participant's own movement.
3.) Break (1 minute)
4.) 2nd round of the interaction with the computer avatar:
    d. one recording (1 minute) of participant's own movement.
    e. three recordings (1 minute each) of the participant following the virtual avatar.
    f. one recording (1 minute) of participant's own movement.
5.) Break (1 minute)
6.) 3rd round the interaction with the computer avatar:
    g. one recording (1 minute) of participant's own movement.
    h. three recordings (1 minute each) of the participant following the virtual avatar.
    i. one recording (1 minute) of participant's own movement.
7.) Attention measuring task (5 minutes), so-called Trail Making Test [Reitan et al 2004]. During the task, the participant will be instructed to connect (in order given by letters and numbers) a set of 25 dots as quickly and accurately as possible.
8.) Completing questionnaire about the game and interaction with the virtual avatar.

Methods of Data Collection and Analysis:

Primary outcome:
Measured movements in people who are considered at risk of psychosis or who have a newly diagnosed psychotic disorder and in healthy controls or those who are assessed as not having psychosis or a future risk of psychosis. We will use the features of recorded movement as inputs for the classifier as described in [Slowinski et al 2017].

Predictor:
The predictor for classification will be the group (the controls or the service users), clinical diagnosis and results of the CAARMS (i.e. ARMS, psychotic or neither).

Data will be recorded during a single research session. Data analysis will be performed in Matlab (Mathworks)

and will follow classification methodology described in [Slowinski et al 2017]. The classification algorithm uses distances between probability distributions, multidimensional scaling, linear and quadratic discriminants and majority rule. Some modification of the methodology from [Slowinski et al 2017] will be allowed due to different data collection platform in the current study. Data collection platform that will be used in the study was tested on healthy participants [Slowinski et al 2016].

We anticipate that attention and concentration ability may be a confounder in the association between ability to complete the test and risk of psychosis. Therefore, we will measure this using the Trial Making Tests A & B [Reitan et al 2004].

Since the main limitation of the study is the high number of the false positive predictions of ARMS when using the CAARMS, we decided to include healthy control group in the study. This will allow us to analyse and compare the accuracy of classification between following groups:

1. the service users and the controls (students from University of Exeter);
    a. 100 service users and 50 controls
    b. the positive CAARMS (FEP+ARMS) and the controls; less than 100 service users (it is not possible to say how many of the services users will have positive CAARMS results) and 50 controls.
    c. the first episode psychosis (FEP) service users and the controls; less than 100 service users (it is not possible to tell how many of the services users will have first episode psychosis) and 50 controls.
    d. the service users at risk of psychosis (ARMS) and the controls; less than 100 service users (it is not possible to tell how many services users will be assessed as being at risk of psychosis) and 50 controls.
    e. the non-psychotic service users and the controls; less than 100 service users (it is not possible to tell how many services users will have negative CAARMS results) and 50 controls.
2. the positive CAARMS (FEP+ARMS) and negative CAARMS (not FEP+not ARMS). 100 service users ((it is not possible to tell how many services users will be in each group)
3. the ARMS and the FEP; less than 100 service users in total (it is not possible to say how many of the services users will have FEP and how many will be assessed as ARMS).

This analysis will help to determine sample size and procedures for future research.

6 STUDY SETTING

The research setting for this multisite study are the Early Intervention for Psychosis teams (EITs) in AWP and DP NHS trusts and University of Exeter.

The control group will be recruited from the University of Exeter students via leaflets (Participant Information Sheet) and recruitment by the University of Exeter researcher (by contacting collaborators from the Department of Psychology and students at final year projects).

Written consent will be obtained from both groups by the team researcher before collecting any data.

During the study, each participant will take part in one research session. The research session will take place at AWP or DP EIT or at the University of Exeter. The research session at all the sites will be the same.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Being accepted for an assessment for psychosis or risk of developing psychosis in Early Intervention for Psychosis team in Devon Partnership NHS Trust (DPT).

7.1.2 Exclusion criteria

- Lacking capacity to providing informed consent for inclusion. The clinical team will have an opportunity to assess the mental capacity at the CAARMS appointment before the potential participant is approached to request consent to contact. It is anticipated that most potential participants will possess capacity.
- Insufficient understanding of English to follow the test instructions
- Any suspected organic cause of psychosis (i.e. head injury, epilepsy or dementia.)
- Taking antipsychotic medication for longer than 4 months before the start of the study.

7.2 Sampling

7.2.1 Size of sample

100 eligible service users that have been identified as appropriate for assessment for risk of psychosis by the Early Intervention for Psychosis Teams (convenience sampling) and at least 50 control participants (University of Exeter students) with approximately the same age structure as the clinical group.

The samples size of 100 service users should allow us to capture sufficient, for this feasibility study, sample of service users referred to EITs with various CAARMS outcomes (ARMS, FEP, not FEP, not ARMS).

Based on two of the experiments in the proof-of-concept study we think a total sample size of 150 is sufficient to assess accuracy of the classifiers and to test study procedures. The data collected in the study will be used to estimate the sample size required for developing robust classifiers for the diagnostic purposes and to inform design of a clinical system. To determine sample size required for clinical study we will follow methodology presented in [Figueroa et al 2012, Beleites et al 2013, Dobbin et al 2006, de Valpine et al 2009].

7.2.2 Sampling technique

Convenience sampling – we want to proceed with the study as quickly as possible, we will approach all eligible participants that have been identified as appropriate for assessment for risk of psychosis by the Early Intervention for Psychosis Team.

7.3 Recruitment

7.3.1 Sample identification

The point of recruitment will be during assessment for risk of psychosis (CAARMS). Potential participants will be identified by the clinical team who will check that they meet the inclusion criteria and make the first contact during their CAARMS appointment.

Only the clinical care team of the patient will access medical records to determine the eligibility of patients.

Clinical participants will be offered 10GBP for taking part in the study. If necessary reimbursement of reasonable travel expenses will be offered (after producing a receipt).

7.3.2 Consent

All the written materials (information sheets and consent forms) will be approved by the REC and NHS trust.

The service users referred for assessment of risk of psychosis will be first approached by a member of their existing clinical care providers from the early intervention centres. They will be provided with a written information sheet.

At the informed consent appointment, before a research session, there will be time for a participant to ask further questions and written consent will be obtained by a team researcher.

Participants will have time for consideration from the time of being approached by their clinical care providers until the scheduled research session. They can also decide to withdraw at any time during the research session without compromising their care or the assessment process.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

There are no risks involved in taking part in this research. During the game-like activity, participants might get tired. There will be a short break in between the three mirror task sessions.

To manage any issues or potential harm, a clinician will be present at all times during the research session.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion and approval will be sought from an NHS REC through the HRA assessment process to obtain HRA Approval. We will also obtain all the necessary research governance permissions and approvals from University of Exeter, AWP and DPT NHS Trust.

Furthermore:

- Substantial amendments that require review by NHS REC will not be implemented until that review is approved and in place and any regulatory other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- The Principal Investigator or designee will notify the REC of the end of the study.
- Within one year after the end of the study, the Principal Investigator or designee will submit a final report with the results, including any publications/abstracts, to the REC. Since the study is planned for less than 12 months there will be no annual reports.
- If the study is ended prematurely, the Principal Investigator or designee will notify the Sponsor and REC, including the reasons for the premature termination.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Principal Investigator or designee will ensure that appropriate regulatory approvals from participating organisations are in place.

For any amendment to the study, the Principal Investigator or designee, in agreement with the Sponsor and funder will submit information to the appropriate body in order for them to issue approval for the amendment. The Principal Investigator or designee will work with sites so they can put the necessary arrangements in place to implement the amendment and to confirm their support for the study as amended.

Amendments

Decision about amendments and if the amendments are substantial or non-substantial will be made by the Study Steering Group and will follow the HRA's most recent guidance on deciding whether an amendment is substantial or non-substantial. The study steering group will follow the detailed instructions from the amendments help section in the Integrated Research Application System (IRAS) on submission of amendments.

8.3 Peer review

The proposal for the study was reviewed within the University of Exeter by the EPSRC Funding panel (approved and proportionate form of peer review for a small feasibility study).

Methods for the study were published in peer reviewed journal article (they were reviewed by two independent, international, expert reviewers) [Slowinski et al 2016, 2017]

The study protocol was reviewed by all the members of the study steering group who are established experts in their respectable fields (psychiatric epidemiology, mental health care, data analysis, mathematics for healthcare). In the study steering group opinion internal peer-review is expert and proportionate. This is a small feasibility study and the protocol is based and closely follows to peer reviewed publication [Slowinski 2016, Slowinski 2017].

8.4 Patient & Public Involvement

<u>The acceptability of the research</u>

We have ensured patient and public involvement by having one co-applicant (Mr Bradley Jones, AWP NHS Trust, Peer Support Worker) and one collaborator (Ms Martha Sneyd, co-Director of Psychosis Health Integration Team) with lived experience of psychosis.

Additionally, Psychosis Health Integration Team (HIT) Service User (SU) forum members have been consulted on the usefulness and acceptability of using this technology to help detect those at risk of psychosis.

Design of the research
We have ensured patient and public involvement by having a co-applicant (Mr Bradley Jones, AWP NHS Trust, Peer Support Worker) with lived experience of psychosis.

Management of the research
We have ensured patient and public involvement by having a co-applicant (Mr Bradley Jones, AWP NHS Trust, Peer Support Worker) with lived experience of psychosis.

Dissemination of findings
We have ensured patient and public involvement by having one co-applicant (Mr Bradley Jones, AWP NHS Trust, Peer Support Worker) and one collaborator (Ms Martha Sneyd, co-Director of Psychosis Health Integration Team) with lived experience of psychosis.

Ms Sneyd will ensure that the opinions of the Psychosis HIT SU forum are sought at all stages of the project and seek their views on dissemination of findings.

8.5 Protocol compliance
Any accidental deviations from the protocol will be documented and reported immediately to the Principal Investigator. Deviations from the protocol which occur frequently, will result in immediate intervention and halting of the study. The study will be continued only after setting appropriate precautions by the study steering group.

8.6 Data protection and patient confidentiality
All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 (or any subsequent revisions of this Act) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Only a member of the patient's existing clinical care team will have access to patient records without explicit consent to identify potential participants, check whether they meet the inclusion criteria and to make the initial approach to patients.

Data collected during the research session will be anonymised by using a study identifier in the presence of the health care professional who will be present during the research session. The service users' written consent forms will be kept at the NHS sites. Data-set accessed by the researchers from University of Exeter involved in the study will include identifier, recorded movements, results of the trail making test, the CAARMS score, clinical diagnosis, information about antipsychotic medication, age, gender, questionnaires with opinions about the interaction with the computer avatar.

Data access will be managed by the Principal investigator. Data will be recorded on a dedicated, password-protected encrypted laptop computer owned and managed via services provided by the University of Exeter. After the study ends anonymised research data will be stored at University of Exeter data repositories. In line with the University's Open Research approach http://www.exeter.ac.uk/research/openresearch/

Research data storage may be extended if follow up studies get funded. The data custodian will be University of Exeter.

8.7 Indemnity
University of Exeter indemnity scheme will apply to the management of the research and the design of the research.

University of Exeter and NHS indemnity scheme will apply to the conduct of the research.

8.8 Access to the final study dataset
Data will be recorded on dedicated, password-protected encrypted computers. Anonymized data will be stored and managed via services provided by the University of Exeter. In line with the University's Open Research approach http://www.exeter.ac.uk/research/openresearch/

Medical data will only be accessed by the patient's existing clinical care team. Researchers from University of Exeter will only have access to anonymised participant's age, gender, medication information, CAARMS score,

movement data, results of the trail making test and to questionnaire data.

9 DISSEMINATION POLICY

9.1 Dissemination policy

Data collected in the study will be owned by Universities of Bristol and Exeter.

The data will be analysed and tabulated and a Final Study Report prepared and send to NHS REC within 12 months after end of the study. Study Report will be also available upon request from the sponsor (the Principal Investigator, University of Exeter).

Depending on significance of the findings the study steering group will make all decision concerning any publications of the results. Additionally, dissemination of findings will be advised by the opinions of the Psychosis Health Integration Team service user forum.

Funders of the study will be acknowledged in all the publications of the study results.

Re: Intellectual Property:

Any potential Intellectual Property generated from the research will be handled through the University of Exeter's Intellectual Property and Commercialisation policies and procedures;
http://www.exeter.ac.uk/research/toolkit/sharing/ip/

9.2 Authorship eligibility guidelines and any intended use of professional writers

We will follow good practice and University guidelines on the matter of authorship of any publications. Any study reports will be co-authored by all study collaborators.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

CVs of the research team

- CV: Krasimira Tsaneva-Atanasova

Additional documents:

- Patient Information Sheet on headed paper (for service users)
- Patient Information Sheet on headed paper (for controls)
- Consent form
- Questionnaire

11.2 Appendix 2 – Schedule of Procedures (Example)

Procedures	**Visits: one or two**		
	Screening (the CAARMS appointment)	**Informed consent appointment**	**Research session**
First contact	X		
Informed consent		X	
Interaction with a computer avatar			X
Trail making test			X
Questionnaire			X

13.3 Appendix 3 – Amendment History

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**