

# The HELPER programme (Healthy Living and Prevention of Early Relapse): Phase 2: INTERACT

<b>Submission date</b> 27/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/02/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
5215

# Study information

## Scientific Title

The HELPER programme (Healthy Living and Prevention of Early Relapse): Phase 2: INTERACT

## Acronym

HELPER (INTERACT)

## Study objectives

Our phase 1 work has led us to develop a 12mth healthy living intervention for patients who have experienced their 1st episode of psychosis in the past 3yrs, who are attending the early intervention service, & who have a BMI of > 25 (24 for people of South Asian origin. The intervention will focus on increasing activity and improving diet.

As of 15/11/2011 this study is in follow-up and the anticipated end date has been updated. The previous end date was 01/12/2010.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

MREC approved (ref: 09/H1016/20)

## Study design

Multicentre randomised interventional treatment trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Topic: Mental Health Research Network; Subtopic: Psychosis; Disease: Psychosis

## Interventions

Increasing activity and improving diet.

Follow up length: 12 months

Study entry: Single Randomisation only

## Intervention Type

Other

## **Phase**

Phase II

## **Primary outcome measure**

Body Mass Index (BMI)

## **Secondary outcome measures**

1. Adherence to medication (Brief Adherence Rating Scale)
2. Depression (Calgary Depression Scale)
3. Health status (36-item short form health survey [SF-36])
4. Level of daily activity (short form International Physical Activity Questionnaire)
5. Quality of life (EQ-5D)
6. The Illness Perceptions Questionnaire for Schizophrenia (IPQ-S)
7. Waist-circumference

## **Overall study start date**

01/06/2009

## **Completion date**

30/04/2012

# **Eligibility**

## **Key inclusion criteria**

1. Aged 16 - 35 years, either sex
2. Diagnosis of schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, brief reactive psychosis, or psychosis not otherwise specified, determined using a checklist of criteria and review of case notes.
3. First episode of psychosis occurred within 3 years preceding the trial
4. Current user of an early intervention service
5. Have stable accommodation (i.e. not street homeless or roofless)
6. Able to give informed consent
7. Have a body mass index (BMI) of greater than 25 kg/m<sup>2</sup>, or a BMI of greater than 24 kg/m<sup>2</sup> for service users from the South Asian community

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

Planned sample size: 104; UK sample size: 104

## **Key exclusion criteria**

1. Diagnosis of substance dependence or abuse as determined from a review of case notes. Sub-diagnostic levels of substance use or abuse will not exclude people from the trial.
2. Have a significant history of organic factors implicated in the aetiology of psychotic symptoms

**Date of first enrolment**

01/06/2009

**Date of final enrolment**

30/04/2012

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Lancashire Care NHS Foundation Trust

Preston

United Kingdom

PR5 6AW

## Sponsor information

**Organisation**

Lancashire Care NHS Foundation Trust (UK)

**Sponsor details**

Sceptre Point

Sceptre Way

Walton Summit

Preston

England

United Kingdom

PR5 6AW

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.lancashirecare.nhs.uk/index.php>

**ROR**

<https://ror.org/03zefc030>

# Funder(s)

## Funder type

Government

## Funder Name

National Insititue for Health Research (NIHR) (UK)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2014		Yes	No
<a href="#">Results article</a>	results	25/04/2018		Yes	No