

# 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
<b>Registration date</b> 27/10/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/02/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

Body Mass Index (BMI)

## **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**  
Lancashire Care NHS Foundation Trust  
Preston  
United Kingdom  
PR5 6AW

## Sponsor information

**Organisation**  
Lancashire Care NHS Foundation Trust (UK)

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

## Funder(s)

**Funder type**  
Government

**Funder Name**  
National Insititue for Health Research (NIHR) (UK)

## Results and Publications

**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