

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

Submission date 27/10/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/10/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/02/2019	Condition category 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

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/m², or a BMI of greater than 24 kg/m² 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?
Results article	results	01/05/2014		Yes	No
Results article	results	25/04/2018		Yes	No