Health-related interventions to improve health and wellbeing and reduce overweight, obesity and unemployment

Submission date 23/02/2021	Recruitment status No longer recruiting	[_] Prospectively [X] Protocol
Registration date 24/02/2021	Overall study status Completed	 [] Statistical ana [] Results
Last Edited 13/02/2024	Condition category Other	 Individual par Record updat

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Plain English summary of protocol

Background and study aims

The increasing rate of obesity and overweight is of great concern worldwide and obesity is rising in the UK, leading to growing concerns over its long-term impact on health. Obesity and overweight put people at risk of serious illnesses such as heart disease, stroke, diabetes, lung disease, cancers and premature death. Additionally, there are economic costs to the healthcare system. In England, high levels of obesity coincide with high rates of unemployment and low income. Fresh, local, healthy food options are often expensive and may be more difficult to cook. This results in many people with low income consuming more highly processed or convenience foods which put them at risk of becoming overweight or obese. While there is a clear link between unemployment and overweight or obesity, current health and employment services rarely work together to tackle the issues as one problem. Individuals struggling with their weight or wellbeing can have difficulties finding work due to a lack of self-confidence and feeling the pressures of stigma. On the other hand, a person who is out of regular work or activity may also struggle to maintain a healthy weight.

The ASPIRE project will help individuals who are unemployed or living with overweight or obesity grow fresh produce, learn new skills, improve their diet, physical activity and wellbeing, as well as increase their employability and employment prospects.

Who can participate?

Adults (18 years or above [UK], 16 years or above [France]) who are unemployed or living with overweight and obesity.

What does the study involve?

Participating in ASPIRE will require regular visits to the ASPIRE hub to take part in activities organised at the hub. Activities will be centred around healthy lifestyle activities which will help participants to eat healthy, grow healthy produce and engage with their community. You can choose to participate in activities within different themes namely: 'Grow your own', 'Eat your own', 'Sell your own' and 'Self-esteem and community'. The activities chosen by participants will depend on the goals they set for themselves with the help of their local ASPIRE coordinator.

What are the possible benefits and risks of participating?

Taking part in ASPIRE will provide participants with some useful information about their health, diet and wellbeing and will help them to practice a healthy lifestyle.

The study is low risk and there will be no adverse effects associated with participation. Participants will be adequately informed about the study, intervention activities and are able to leave the study at any point should they wish to do so.

Where is the study run from?

ASPIRE activities will be implemented at different hubs/community centres located in Medway, Kent and Boscombe (for sites located in the UK) and in Peronne, Wimereux, Abbeville and Viielle Eglise (for the hubs located in France).

When is the study starting and how long is it expected to run for? September 2019 to June 2023

Who is funding the study? The ASPIRE project is funded by EU Interreg European Regional Development Fund (ASPIRE 191).

Who is the main contact? Professor Jane Murphy, jmurphy@bournemouth.ac.uk

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers Nil known

Study information

Scientific Title

Adding to Social capital and individual Potential In disadvantaged REgions

Acronym ASPIRE

Study objectives

Health-related interventions will result in weight loss in adults with overweight and obesity
 Health-related interventions will increase employment in unemployed individuals

Ethics approval required Old ethics approval format

Ethics approval(s)

Approved 14/08/2020, Bournemouth University Research Ethics committee (M402, Melbury House, 1-3 Oxford Road, Bournemouth, BH8 8ES, UK; +44 (0)1202 961073; swignall@bournemouth.ac.uk), ref: 33136

Study design

Multicentre interventional non-randomized study

Primary study design Interventional

Secondary study design

Non randomised study

Study setting(s) Community

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Reduction of body weight and increase in employment in adults who are unemployed or living with overweight and obesity

Interventions

Interventions in ASPIRE will be a combination of healthy lifestyle and skills training to help participants improve their health and wellbeing and ultimately reduce their weight, obtain employment or enter into training or voluntary roles. The activities have been placed under four themes and participants can choose a theme that matches their goals with the help of their local ASPIRE coordinator. The core elements of ASPIRE are listed below:

- Being active via 'grow your own'
- Healthy food and nutrition via 'eat your own'
- Achieving personal goals and improving employability via 'sell your own'
- Self-esteem and support within a community which brings all the different elements together.

ASPIRE activities will include the following: Virtual reality guided meditation, self-care and selfimage support activities, motivational interviewing, positive experience workshops, understanding behaviour change workshops, setting up and maintaining community allotment or personal vegetable patch workshops, walking groups, understanding of seasonal and local food cultivation workshops, fitness and wellbeing classes (yoga, tai chi, mindfulness), diet and nutrition workshops, cooking classes, food shop on a budget tools and support, cooking on a budget/cooking with leftovers resources, sourcing cheaper healthy produce, meal planning, reducing waste and food preservation workshops, cooking with homegrown produce, cooking with limited resources, soft skills recognition and development workshops, links with local business to offer volunteering and work experience, interview preparation: mental and physical via workshops and virtual reality, entrepreneurship support, workshops to define skills (interpersonal skills and know-how), strengths and weaknesses and know how to introduce yourself (in connection with the virtual reality interviews). ASPIRE will have a one group pre-test-post-test design and participants will be followed up over time.

Due to the nature of the ASPIRE project, there is no fixed intervention time. Participants will be allowed to take part in activities until their weight loss or employment goals are met. Some participants may exit the study earlier if they have obtained a job or met their weight goal.

Intervention Type

Behavioural

Primary outcome measure

1. Body weight (kg) and body mass index (kg/m²) is measured using the Interactive Health Kiosk at baseline, 12 weeks, 6 months and 9 months

2. Employment status will be assessed by documenting when a participant obtains remunerated work (full-time and part-time) or subsidised work measured by self-report at baseline, 12 weeks, 6 months and 9 months

Secondary outcome measures

1. Dietary intake and diet quality will be measured using a validated semi-quantitative food frequency questionnaire (FFQ), at baseline, 12 weeks, 6 months and 9 months

2. Self-efficacy will be assessed using The General Self-Efficacy Scale (GSE) at baseline, 12 weeks, 6 months and 9 months

3. Health-related quality of life will be measured using the EuroQol EQ-5D-5L questionnaire at baseline, 12 weeks, 6 months and 9 months

4. Physical activity will be measured using self-reported assessments of physical activity on a 2item questionnaire which reports participants' engagement in light, moderate or vigorous physical activity over the previous week as well as the duration and frequency of the activity at baseline, 12 weeks, 6 months and 9 months

5. Self-reported health status will be assessed using 5-items on the health, wellbeing and activity questionnaire consisting of questions asking participants to rate their physical health over the past 30 days at baseline, 12 weeks, 6 months and 9 months

6. Workability will be assessed using 4-items adapted from the work ability and functional capacity self-assessment questionnaire at baseline, 12 weeks, 6 months and 9 months

Overall study start date 01/09/2019

Completion date 30/06/2023

Eligibility

Key inclusion criteria

1. Individuals who are overweight or obese or unemployed or jobseeker

2. Ability to attend activities at ASPIRE hub in the different implementation sites

3. Adults 18 years and above (16 years for participants in France)

Participant type(s) Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants 1,303

Total final enrolment

331

Key exclusion criteria

1. Terminal illness or palliative care, dementia, a severe mental health problem or learning difficulty.

2. Planned bariatric or weight loss surgery

 Serious psychosocial problems or behavioural problems that could hinder participation in interventions (e.g. drug addiction, serious psychiatric disorders, aggressive delinquent behaviour)
 Pregnant or planning to become pregnant

4. Individuals currently involved in full-time paid employment or recurrent (continuous) short-term contracts

Date of first enrolment

28/09/2020

Date of final enrolment

30/09/2022

Locations

Countries of recruitment England

France

United Kingdom

Study participating centre ASPIRE Aylesham Hub (Your Leisure/Dover District Council) Ackholt Rd Aylesham Canterbury United Kingdom CT3 3AJ

Study participating centre Mission Locale Picardie Maritime Rue Saint Gilles 82 Abbeville France 80100

Study participating centre Maison pour l'Entreprise l'Emploi et la Formation Santerre Haute Somme Rue de la Madeleine 8 Peronne France 80200

Study participating centre Association centre socioculturel Rue de Baston BP 14 42 Wimereux France 62930

Study participating centre Les Anges Gardins Rue du pont d'oye, 800 Vieille Eglise

France 62162

Study participating centre

Boscombe Hub (Bournemouth, Christchurch and Poole Council) Town Hall Bourne Avenue Bournemouth United Kingdom BH2 6DY

Study participating centre Medway Community Healthcare CIC MCH House 21 Bailey Drive Gillingham Business Park Gillingham United Kingdom ME8 0PZ

Sponsor information

Organisation Bournemouth University

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Sponsor type University/education

Website https://www.bournemouth.ac.uk/

ROR https://ror.org/05wwcw481

Funder(s)

Funder type Government

Funder Name EU Interreg European Development Fund

Results and Publications

Publication and dissemination plan

Planned publication of results in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	realist evaluation protocol	24/03/2021	27/04/2021	Yes	No