

Brief health promotion intervention in walk-in unit: Randomised controlled trial

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Submission date 13/07/2017 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 03/08/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 30/07/2019 | Condition category Respiratory | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Long term conditions specifically heart disease, cancers, respiratory diseases and type 2 diabetes are major causes of non-accidental premature deaths before the age of 65. They are strongly linked to avoidable risky lifestyle behaviours explicitly obesity, smoking and overuse of alcohol. Locally, the health of people in Portsmouth is stated to be varied compared to England average. There are 23% people that smoke 24%, that over use alcohol and 52% that are overweight and obese. Health promotion and public health interventions are needed to improve the state of health for the people in Portsmouth. The local minor injuries and illness unit has not previously been involved in proactive opportunities brief health promotion. As patient usually has to sit for a long time and wait for an appointment at local minor injuries and illness units, this provides an opportunity to make a difference and utilize the time patient spending waiting to provide health promotion, especially as men are known to delay in seeking medical services. A referral to a Wellbeing service in the area could be beneficial for those who smoke, overuse alcohol, and are overweight as these are avoidable causes of premature death and long term health conditions. The aim of this study is to explore the feasibility, acceptability and effectiveness of the implementation of opportunistic brief health promotion intervention on smoking, alcohol and obesity at the local minor injuries and illnesses walk in centre.

Who can participate?

Adults aged between 16 to 75 who are not already under services for management of diabetes.

What does the study involve?

Participants are randomly allocated to one of three groups at time of consultation with the study team. Those in the first group receive an immediate intervention within 20 minutes of their consultation which includes a health conversation about their risky life style behaviour, assess readiness to change behaviour, an information leaflet and a referral. Those in the second group receive the same as the first group; however they do not receive an offer of referral and instead have a delayed offer of referral with a nurse practitioner around 10-240 minutes after the consultation. Those the first group do not receive an intervention at the initial consultation but receive it during a consultation 10-240 minutes after. There is no follow up for participants.

What are the possible benefits and risks of participating?

Participants may benefit from receiving information on how to change their unhealthy lifestyle behavior and be referred to the free Wellbeing services. There are no risks with participating, however some of the questions may be felt as sensitive as they ask about alcohol, weight and smoking.

Where is the study run from?

St Mary's NHS Treatment Centre (Portsmouth)

When is the study starting and how long is it expected to run for?

October 2014 to July 2017

Who is funding the study?

Investigator initiated and funded (UK)

Who is the main contact?

Cindy Chacha Mannie

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Contact information

Type(s)

Public

Contact name

Ms Cindy Chacha Mannie

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A pragmatic single blinded randomised control trial to explore the effectiveness of immediate and delayed brief health promotion intervention (smoking cessation, weight management and alcohol intervention) among 16-75 year old at risk clients presenting to a minor injuries and illnesses unit

Study objectives

Immediate intervention, written information and time to reflect will increase the uptake of referrals to Wellbeing services at consultation stage.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Northern Ireland Ethics Proportionate review, 18/06/2015, ref: 15/NI/0123

Study design

Feasibility utilising mixed methods on smoking, BMI 25 and over, overuse of alcohol brief healthy conversation and offer of referral

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet Cindy Chacha Mannie at cindy.chacha@careuk.com

Health condition(s) or problem(s) studied

Screening for smoking status, asking about weight and height to calculate BMI and overuse of alcohol 28 units for men at the time . After screening and mostly self reported on adapted form. They were offered brief health conversation, asked if read to change, offer to refer to Well being Service

Interventions

Eligible participants who fill out the self-declared behaviour (smoker, BMI 25 and over and alcohol over 21-28 units at the time) on the mandatory booking-in-form receive an immediate consultation where they are invited to join the study. After signing consent, participants are

randomised using sealed envelope in a box. Treatment then continued as planned, immediate, or immediate with no offer of referral but time to thing and delayed intervention

The three arms include:

Arm A1: Participants receive immediate intervention, within 20 minutes of initial consultation (healthy conversation about risky lifestyle behaviour), information, assess for readiness to modify behaviour, written leaflet on specific behaviour and offer of referral.

Arm A2: Participants receive immediate intervention within 20 minutes of initial consultation (healthy conversation about risky lifestyle behaviour), information, assess for readiness to modify behaviour, written leaflet on specific behaviour and NO offer of referral, rather delayed offer of referral with nurse practitioner at time of full consultation which can be 10-240 minutes waiting time from initial assessment.

Arm B: Participants do not any intervention at initial consultation but are given the intervention (healthy conversation about risky lifestyle behaviour), information, assess for readiness to modify behaviour and written information leaflet on the specific behaviour during full consultation 10 minutes-240 minutes waiting time from initial assessment.

Consistency in intervention was important while taking into consideration individuality of clients and nurse practitioners.

There was no follow up of participants. Intervention ended at the end of a consultation. Participants that were followed up were only those that were referred to the Wellbeing service. They were followed up by the Wellbeing service after we emailed the referral form

Intervention Type

Behavioural

Primary outcome measure

Number of referrals done are measured using the referral forms attached to the research checklist at the end of the consultation.

Secondary outcome measures

Time taken to have the healthy conversation is measured by using the mean and mode from the time taken as recorded by the clinician on the research checklist form at the end of the consultation.

Overall study start date

25/10/2014

Completion date

17/07/2017

Eligibility

Key inclusion criteria

1. Aged between 16 and 75
2. English speaking
3. Not already under secondary services namely management of diabetes

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

204

Total final enrolment

204

Key exclusion criteria

1. Emergencies
2. Language barrier- offered service but not included in study
3. Mental ill health

Date of first enrolment

01/07/2015

Date of final enrolment

16/12/2015

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

St Mary's NHS Treatment Centre

Minor Injuries and Illness Unit

Milton Road

Portsmouth

United Kingdom

PO3 6DW

Sponsor information**Organisation**

University of Portsmouth

Sponsor details

James Watson West
2 King Richard 1st Road
Portsmouth
England
United Kingdom
PO1 2FR
+44 2392844426
ann.dewey@port.ac.uk

Sponsor type

University/education

Website

<http://www.port.ac.uk/>

Organisation

St.Marys NHS Treatment Centre

Sponsor details

Care UK
Milton Road
Portsmouth
England
United Kingdom
PO3 6DW
+44 239 285 8429
penny.daniels@careuk.com

Sponsor type

Hospital/treatment centre

Website

www.stmarystreatmentcentre.nhs.uk

Organisation

University of Portsmouth

Sponsor details

Sponsor type

Not defined

Website

<http://www.port.ac.uk/>

ROR

<https://ror.org/03ykbk197>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Peer reviewed journals, walk in centre new letter, conferences, intention to publish all findings, the profile to explore kind of clients that use the service, the randomized controlled trial results and the qualitative findings.

Intention to publish date

31/12/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Cindy Chacha Mannie at cindy.chacha@careuk.com

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Basic results | | 11/10/2018 | 11/10/2018 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |