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We Can Quit2 (WCQ2): a community-based programme to help women living in disadvantaged areas of Ireland to stop smoking

Submission date
24/09/2018

Recruitment status
No longer recruiting

Registration date
29/03/2019

Overall study status
Completed

Last Edited
27/09/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Smoking rates remain high in Ireland despite considerable progress being made to reduce them in recent years. Ireland ranks second highest for smoking-related causes of death in the EU. Lung cancer, which is strongly linked to smoking, is now the most common cause of death for women in Ireland particularly those living in more disadvantaged areas. Due to this, the Irish Cancer Society developed a new stop smoking programme for women in 2012 called 'We Can Quit' (WCQ) which was established following a review of the literature conducted by members of our research team. We also undertook a small study to look at initial stop smoking rates from WCQ when it was first set up. There is now a need to conduct a bigger study to research this programme. This current research proposal is for a pilot of 'We Can Quit 2' (WCQ2).
We will now conduct a study comparing WCQ2 with the existing stop smoking services 'usual care' provided by the Health Service Executive (HSE) in Ireland.

Who can participate?
Adult women who are daily smokers and have an interest in quitting

What does the study involve?
One district in each pair will provide WCQ2 and the other usual care. Women who agree to take part will be asked to attend according to their district. WCQ2 is a group programme and will be delivered by community workers (Community Facilitators) trained in helping people to stop smoking. The HSE service will be delivered by trained Stop Smoking Officers and women will receive one-to-one help. Women will be asked to fill in a questionnaire at the start and end of the programme and then at 6 months after the start of the programmes. They may also be asked to take part in an interview just after they finish the programme. At the same time as the study is taking place we will look at the activities (processes) to make sure the programme is of high quality. At the end of the study we will look to see how the results can be used and if we need to do a bigger study involving more districts and more women.

What are the possible benefits and risks of participating?
The possible benefit of participating is that women may succeed in stopping smoking, which

means they can expect that breathing may get better as well as ability to exercise. They can expect to have more money, better skin and hair and a lower risk of heart disease, stroke and cancer. They will also help researchers and healthcare staff to learn how to best support women to quit smoking.
There are no major risks to taking part in this study. However, some women may experience withdrawal symptoms, such as cravings to smoke, or minor side effects from nicotine replacement therapy. These will be dealt with by the Community Facilitator, Stop Smoking Officer or pharmacist.

Where is the study run from?
Trinity College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
June 2017 to August 2019

Who is funding the study?
Health Research Board Ireland (Ireland)

Who is the main contact?
Professor Catherine Hayes
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
DIFA-2017-048

Study information

Scientific Title

Peer-delivery of a gender-specific smoking cessation intervention for women living in disadvantaged communities in Ireland We Can Quit2 (WCQ2) - a pilot cluster randomized controlled trial

Acronym
WCQ2

Study objectives
To assess the feasibility of running a definitive randomised trial to determine whether a community- smoking cessation intervention tailored to disadvantaged women affects smoking cessation rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Dublin, Trinity College School of Medicine Research Ethics Committee, 03/05/2017, ref: 20170404

Study design
Interventional pragmatic two-arm single-centre parallel-group cluster randomised pilot feasibility study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Four matched pairs of districts (eight clusters), will be randomised with each matched pair of clusters randomised to intervention or controls in a 1:1 allocation ratio. The randomisation will follow a pragmatic approach whereby paired districts ready for the intervention will be randomised first, followed by the next available matched pair; this accounts for temporal changes over time and will provide a balanced design.
The randomisation will be conducted remotely by the Wellcome Trust Clinical Research Facility (CRF) independent of the Trial Management Team, who will have developed a Standard Operating Procedure (SOP) for this process. The code for each matched pair of districts will have been concealed and securely stored by the Wellcome-CRF. It will be revealed to the WCQ2 trial team once sufficient numbers have been recruited (or by agreement with the Trial Management Group (TMG)) if recruitment is insufficient prior to intervention delivery). Practitioners will be informed of their allocation by the research team and and participants will be informed of their allocation by the practitioners.
Participants randomised to the intervention will receive 12 weekly behavioural support group sessions and Nicotine Replacement Therapy (NRT). The group sessions are designed to enhance positive social support systems among peers. NRT is made available without cost to all intervention participants.

Each programme will be delivered in a local community facility by two trained Community Facilitators (CFs) who tend to be ex-smokers themselves. Each session will last approximately 90 minutes. The CF's will make proactive personal contact both during and between sessions with participants using their own language and cultural style and provide opportunity to share testimonials and personal experiences. They also carry out regular Carbon Monoxide (CO) monitoring.
Participants will be followed up at end of programme (12 weeks) and at 6/12. Salivary cotinine +-anabasine to biochemically validate self-reported smoking cessation will be recorded at week 12 and at 6/12.
Participants randomised to the control arm will receive a standard face-to-face smoking cessation programme offered by the national health service in Ireland to men and women (Health Service Executive – HSE) delivered by a Smoking Cessation Officer [21]. This service model is not available in all areas but was chosen as it offers a face to face service rather than simply telephone or online support, and monitoring data were readily available.
This programme encompasses, on average, six to seven individual sessions offered in a primary care centre or hospital outpatient clinic. Sessions vary in duration and mode of delivery, however, the first of these is delivered face-to face (average session length between 30 - 45 minutes). Subsequent visits occur weekly or every two weeks and may be conducted by telephone.
Similar to WCQ the components of the behavioural support elements of the HSE programme include, reinforcing motivation to quit and setting a quit date, building a repertoire of client coping strategies, providing information on the nature of tobacco addiction and withdrawal, undertaking regular carbon monoxide checks and giving feedback on progress, planning ongoing coping mechanisms and support. Clients are informed about Nicotine Replacement Therapy and other smoking cessation pharmacotherapies. HSE clients will obtain these free of charge if they are eligible for General Medical Services (GMS).
Participants will be followed up at 12 weeks and at 6/12. Salivary cotinine +-anabasine to biochemically validate self-reported smoking cessation will be recorded at week 12 and at 6/12.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility of recruitment, assessed by the number of women enrolled in the study as a proportion of the recruitment target of 194 women from eight randomised districts within 18 months during four 12 week periods

Key secondary outcome(s))
1. Retention and data completion rates in each trial arm at 12 weeks and 6 months post quit date as a follow-up timepoint in the full trial. Retention will be measured as the number of women retained in the study by 12 weeks and six months post quit date as a proportion of the number of women enrolled.
Data completion will be measured as the proportion of valid sets of outcome measures completed by women at 12 weeks and six months post quit date.
2. Proportion of participants who are continuously abstinent from smoking (as per Russell Standard), at 12 weeks. This will be measured by self-report corroborated by salivary cotinine and anabasine.
3. Proportion of participants who are continuously abstinent from smoking, at 6 months after their quit date, corroborated by salivary cotinine and anabasine.
4. Proportion of enrolled smokers who engage with smoking cessation services in each trial arm (engagement is defined as arrival for a first with a smoking cessation adviser and having set a

quit date). This will be measured by the proportion of women who have set a quit date up to and including the second session with a smoking cessation advisor as a proportion of those who enrolled in the study
5. Proportion of participants who report improvement in health status measured at baseline (week 1) and 12 weeks and 6 months. This will be measured by calculating the number and percentage of responses for each item of the 12-item short-form health survey (SF-12) at week 1, week 12 and 6 months. Means, standard deviations (or their non-parametric alternative) will be estimated together with the corresponding change scores and effect sizes.
6. Fidelity to and adaptation of the intervention as established by Community Facilitator checklist and diary assessed at time of focus group interview at week 12.
7. Acceptability of trial processes by participants and practitioners involved in service delivery as established by interviews at week 12.
8. Assessment of the trial design across a range of pre-designed measures PRECIS 2 during intervention delivery and at the end of the intervention and ADePT (A process for Decision-making after Pilot and feasibility Trials) decision aid will be used at the end of the intervention to aid the decision-making process around progression to the full trial.

Completion date
26/08/2019

Eligibility

Key inclusion criteria
1. Female
2. Aged 18 or over
3. English speaker
4. Self-reported as a daily smoker with an interest in quitting
5. Deemed to live/work within easy travel distance of the trial catchment areas
Women taking Nicotine Replacement Therapy (NRT) or who are have been prescribed bupropion /varenicline by the doctor at time of recruitment are eligible to take part, as are women using e-cigarettes.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
208

Key exclusion criteria
1. Pregnant or planning a pregnancy in the near future
2. Enrolled in another smoking cessation study
3. Cannot travel to location of programme delivery
4. Do not have the capacity to give informed consent

Date of first enrolment
18/01/2018

Date of final enrolment
06/02/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Institute of Population Health
Russell Centre
Tallaght Cross
Dublin
Ireland
D24 DH74

Sponsor information

Organisation
Trinity Research & Innovation, Trinity College Dublin

ROR
https://ror.org/02tyrky19

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)

Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 14/06/2022:
The anonymized quantitative data are expected to be made available on the Irish Social Services Data Archive (ISSDA). The overall arrangements for this are as yet not completed. However, the ISSDA licence agreement has been drawn up. There is no weblink.
Applicants wishing to use quantitative data will need to apply for approval by ISSDA. Qualitative data will not be made available.
Access to the dataset will be permitted under certain conditions and regulated according to the ISSDA terms of use. Access will be for research purposes only. Researchers accessing the dataset will be required to conduct studies related to WCQ2, such as tobacco or other related health research. Researchers willing to access and use the dataset must sign a legally binding End User License as per ISSDA requirements. For more information, see the ISSDA webpage (https://www.ucd.ie/issda/depositdata/). The timing for availability is not yet agreed.
Women participating in the WCQ2 trial provided informed consent to the use of their personal data before randomisation and baseline data collection. They did not give explicit consent to share their data after study completion for further unrelated research use.
However, the General Data Protection Regulations in Ireland allow the further use of data without looking for explicit participant consent only if data are irreversibly anonymised.
The quantitative data have been irreversibly anonymised. Two groups of anonymisation techniques have been applied: Removing personally identifiable information and Aggregation or k-anonymity.
An amendment to the WCQ2 study ethical approval (Reference number 20170404) will be sent for consideration to the School of Medicine Research Ethics Committee, Trinity College Dublin. The content of this amendment will state the reasons and general procedure to share fully anonymised trial quantitative data with the ISSDA for its long-term preservation. This has yet to be completed.
The qualitative dataset will not be made available as explicit participant consent was not obtained.

Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are not expected to be made available due to explicit participant consent not being obtained for this.

IPD sharing plan summary
Stored in publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2022	14/06/2022	Yes	No
Results article	Process evaluation	10/08/2022	12/08/2022	Yes	No
Results article		20/11/2021	27/09/2022	Yes	No
Protocol article	protocol	23/11/2019	27/11/2020	Yes	No
Protocol article	systematic review protocol for community smoking cessation trials in low-income women	12/06/2019	04/01/2021	Yes	No
Abstract results	abstract on the recruitment strategies and lessons learned from the WCQ2 trial, presented at the Society for Social Medicine annual meeting :	01/09/2019	04/01/2021	No	No
Abstract results	abstract on preliminary findings of the WCQ2 trial, presented at the SSM-PH Annual Scientific Meeting 2020	09/09/2020	16/11/2021	No	No
Abstract results	abstract on results of the trial knowledge exchange and dissemination strategy of the WCQ2 trial, presented at SSM-PH Annual Scientific Meeting 2021	04/09/2021	16/11/2021	No	No
Abstract results	abstract on rresults of the trial process evaluation of the WCQ2 trial, presented at 14th European Public Health (EPH) Conference 2021	20/10/2021	16/11/2021	No	No
Abstract results	abstract on the preliminary findings from the WCQ2 trial, presented at the 11th EU Public Health Association (EUPHA) Meeting 2020	13/11/2019	16/11/2021	No	No
Other publications	Retrospective evaluation of the WCQ2 pilot trial design	25/01/2022	27/01/2022	Yes	No
Other publications	Knowledge Exchange and Evaluation	18/02/2022	14/06/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results	Accompanying process evaluation results	22/12/2021	14/06/2022	No	No
Study website	includes trial policy brief	16/11/2021	16/11/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes