A Process Evaluation of 'We Can Quit': a Community-Based Smoking Cessation Intervention Targeting Women From Areas of Socio-Disadvantage in Ireland

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Abstract

Background: Smoking poses a serious risk of early preventable death and disease especially for women living with socio-economic disadvantage (SED). A smoking cessation programme 'We Can Quit' was developed in Ireland tailored to SED women. The programme includes group-based support delivered by trained lay local women and free nicotine replacement therapy (NRT). The intervention was pilot tested in a cluster randomised controlled trial, 'We Can Quit 2'. A process evaluation assessed feasibility and acceptability of the programme and trial processes.

Methods: Embedded qualitative design using the Medical Research Council's (MRC) process evaluation framework. Semi-structured interviews with trial participants (N=18) and programme deliverers, the community facilitators (CFs; N=8). Thematic analysis was used for interview transcripts.

Results: Results focused on programme and trial operational factors. Peer-modelling, a non-judgemental environment, and CFs supportive role of group support were viewed as facilitative. Potential for broader message diffusion into the social networks of participating women was observed. Free NRT was helpful for cessation. Some participants expressed concerns about NRT side effects. Community pharmacists provided guidance relating to NRT and additional support between programme meetings. Provision of saliva samples proved challenging. Low literacy was a barrier for engagement with programme and trial-related materials. Hypothetical scenarios of direct or indirect observational fidelity assessment for a future definitive trial (DT) were acceptable.

Conclusions: The We Can Quit intervention and trial-related processes were feasible and acceptable to participants and Community Facilitators. Any future DT will need to address low literacy.

Trial registration: Controlled trials ISRCTN74721694.

Background

Tobacco use is the main cause of preventable death worldwide (1) and has been causally related to a variety of chronic diseases and fourteen types of cancer (2), including lung cancer (3). In Ireland, as in most high-income countries, smoking prevalence and associated health consequences are greater in socioeconomically disadvantaged (SED) populations (4–6). These health inequalities are associated with psychosocial factors, such as high daily stress, lack of social support, and pro-smoking social norms (7–9).

Gender is also a determinant of smoking (10). A review of evidence from effectiveness trials have indicated that women are less likely to quit smoking and have more difficulty maintaining long-term smoking abstinence than men (11). In Ireland, this is reflected in increased lung cancer incidence among women between 1994-2015. Lung cancer is now the main cause of mortality from cancer in women in Ireland (12, 13).

Smoking in women is related to SED (14). The link between disadvantage, gender and smoking status is recognised by the World Health Organization (WHO) Framework Convention on Tobacco Control that argues tobacco control strategies should be tailored to disadvantaged women to reduce smoking prevalence and associated illness (4). These strategies should address individual aspects of smoking and socio-economic factors (10, 15).

Social support has been recognised as facilitating smoking cessation (16). Smokers from SED groups, and women in particular, usually experience a lack of social support for smoking cessation from their personal environment and from available cessation aids (7, 9, 10). Addressing social support needs of SED women may be key to improving smoking cessation (10, 17).

Group-based behavioural interventions involve the delivery of behavioural techniques, specific advice, and support from other participants (18). Although group support is more effective than self-help, more evidence is needed to determine its effectiveness compared to intensive individual counselling and in sub-groups of smokers (19), such as SED women. To date, the evidence on the effectiveness of group-based smoking cessation interventions tailored to women is scarce (20–22). Only one previous randomised controlled trial (RCT) has evaluated a group-based cessation intervention tailored to the specific needs of disadvantaged African-American women, with positive abstinence rates (20).

The use of nicotine replacement therapy (NRT) increases the rate of quitting by 50–60%, regardless of setting (23), and can help to prevent smoking relapse (24). The cost of NRT has hindered access and potential benefits to SED smokers (9, 25).

We Can Quit2 (WCQ2) study was a pilot cluster RCT conducted in four matched pairs of SED districts in Ireland to evaluate the feasibility and acceptability of We Can Quit (WCQ), a community-based intervention to address smoking cessation in women delivered by trained lay community facilitators (CFs) (26, 27). It was based on the Socio-Ecological Model (28) and developed using a community-based participatory research approach (29). The primary quantitative results of the WCQ2 pilot study are described elsewhere (30).

Trial evaluations typically focus on understanding whether interventions are effective but cannot explain how and why interventions succeed or fail in attaining outcomes. This is particularly important to definitive trials (DTs) of complex interventions (31). Of growing importance is the need to understand why interventions succeed or fail in the pilot trial phase (such as WCQ2), thereby allowing earlier design adaptations before progression to DT (32). A process evaluation, as outlined by the Medical Research Council (MRC), allows for an assessment of implementation, the identification of contextual factors and proposed mechanisms for change (31). It is considered an essential part of designing and testing complex interventions and complements earlier MRC guidance (33). Hence, a qualitative, mixed-method process evaluation was embedded into the WCQ2 trial, following MRC specific guidance. The aim was to test the robustness of the pilot trial design with respect to context for intervention delivery, implementation processes, and strategies to optimise trial methodology for progression to a full pragmatic DT (27). To our knowledge few smoking cessation feasibility trials have applied MRC process

evaluation guidance, with only one completing a process similar to the current study (34). Others examined acceptability of the cessation intervention only from the perspectives of participants, overlooking the assessment of trial processes acceptability (35)(36).

The current study expands on this important area and presents qualitative findings of the WCQ2 process evaluation. Study objectives were to assess the acceptability of the WCQ intervention, including group-based support and NRT; and of how the trial-related processes differed from real world processes, from the perspectives of participants and CFs.

Methods

Design

This research is embedded within a larger trial which took the philosophical stance of 'pragmatism', which is the most commonly stated philosophy supporting mixed methods research (37–40). Pragmaticism values both objective and subjective knowledge, and investigators using both quantitative and qualitative data, adopt a postmodern viewpoint and employ a reflective lens of the social, environmental, and other contexts at play. In this tradition, knowledge is constructed using data through the adoption of an inductive-deductive logic, thereby increasing the credibility of the research findings (38). This aspect of the trial embraces a qualitative research design, using face-to-face individual and paired interviews was employed, with exploratory social network data collected in the intervention arm as part of routinely collected monitoring data. An inductive approach, where the research team attempted to make sense of context and data without imposing pre-existing expectations on the topic under inquiry, was used (41). Stakeholder interviews are a common method of inquiry as outlined by the MRC's framework to 'capture emerging changes in implementation, experiences of the intervention and unanticipated or complex causal pathways' (31). The School of Medicine Research Ethics Committee, Trinity College Dublin, approved this study (Reference number 20170404). All research procedures have been performed in accordance with the Declaration of Helsinki.

WCQ2 pilot trial overview

The WCQ2 pilot trial primary objectives were to determine feasibility and acceptability of trial processes, including randomisation of districts, recruitment, and data completion rates at 12-week and 6-month follow-ups, essential to inform a future DT of WCQ clinical effectiveness. The trial was registered with the ISRCTN registry (date of first registration: 29/03/2019; registration number: 74721694). Participants were recruited in four consecutive waves, each one in a matched SED district (27). Treatments were the WCQ intervention, which comprised 12 weeks of group-based behavioural support and optional access to NRT without charge for all women. The WCQ intervention also included specific optional advice from community pharmacists to support NRT use. Activities focused on increasing self-efficacy; on peer-support by sharing experiences at sessions and celebrating achievements with family, friends, and the local community (26, 27). WCQ participants also received activity worksheets and were invited to keep a personal smoking diary from the first session to increase the understanding on their smoking behaviour.

The control treatment was one-to-one cessation support delivered by trained clinical staff from the statutory smoking cessation services provided by the Ireland's Health Service Executive (HSE).

Trial quantitative results demonstrated that recruitment of participants into the study was feasible though challenging, as it required the active involvement of community members to achieve the target number of participating women. Retention at follow up was less than expected (30). This trial was registered on 24/09/2018 with the ISRCTN registry no: 74721694.

Selection of participants

A purposive sampling procedure was employed, targeting the key stakeholders involved in the trial – the women who received the intervention and the CFs who delivered it. The focus of participant recruitment was to identify and select information-rich cases (42) from whom it was possible to learn about experiences of programme recipients, the facilitators who delivered the intervention and to elucidate participants' experiences of being involved in a pilot RCT. Key participant characteristics and outcome assessment at follow up are shown in Table 1.

Table 1
Baseline socio-demographic and smoking characteristics of WCQ intervention participants and outcome assessment at 12-week follow-up interview.

Socio-demographics	
Age mean, (SD)	52.1, (10.7)
Marital Status	*n (%)*
Married or cohabiting	11 (52.4)
Not married (single, separated, divorced, widowed)	10 (47.6)
Education	
No formal / Primary / Lower	8 (38.1)
Secondary / Technical or Vocational / Completed Apprenticeship	8 (38.1)
Degree (Diploma, Masters, PhD)	5 (23.8)
Employment	
Full/part time	8 (38)
Not in paid employment	13 (62)
Possession of a medical or GP card	
Yes	15 (71.4)
No	6 (28.6)
Smoking behaviour at baseline	
Reasons for smoking	
For pleasure / to cope	6 (28.6)
Habit / Addicted / Other	15 (71.4)
Time after waking before first cigarette	
Within 5 minutes	14 (66.6)
After 5 minutes	7 (33.3)
Determination to give up smoking	
Quite determined	6 (28.6)
Very / Extremely determined	15 (71.4)

* Three participants did not give any information on NRT use.

** Corroborated by saliva tests.

Socio-demographics	
WCQ delivery	
Attendance to sessions	
Between 1 and 8 sessions	8 (38)
Between 9 and 12 sessions	13 (62)
Used NRT during intervention delivery*	
Yes	12 (57.1)
No	6 (28.6)
Smoking status at 12-weeks (end of programme)**	
Abstinence	8 (38)
Continued smoking	13 (62)
* Three participants did not give any information on NRT use.	
** Corroborated by saliva tests.	

Procedure

At the end of the programme, all participants who attended at least one group session were contacted by telephone and invited for interview. A semi-structured interview schedule allowed for probing, follow-up questions and flexibility. Interview schedules were piloted. (See Additional Files 1 and 2 for sample interview schedules for participants and CFs). Interviews were face-to-face and occurred between June 2018 and May 2019 at times and locations convenient to participants. Only the interviewer (EB; female; MSc-level training; full-time trial research assistant) and interviewees were present. The interviewer was known to interviewees at the time of interviews from previous contact regarding recruitment and follow up within the trial. Each interview lasted on average 20-30 minutes, while CF interviews lasted approximately an hour. Participant interviews were conducted individually, while interviews with CFs (two CFs per intervention site) were conducted together. Interviews were audio recorded and transcribed verbatim by a professional transcriber. Observational field notes were completed to enhance data and provide context for analysis. Informed written consent was obtained prior to commencing interviews and participation was voluntary.

To ensure anonymity, participants were given identification tags (e.g., W1-CF1, which corresponds to Wave 1 of recruitment, Community Facilitator 1; W3-P0004, which corresponds to Wave 3 of recruitment, participant number 0004). Reporting of the study methods have followed published standards for undertaking and reporting qualitative research (COREQ) (43).

Social Network Analysis. Despite not being an explicit objective of the process evaluation, aspects of women's social networks were explored. The objective was to assess the potential and actual extent of

dissemination of programme-related information through women's social networks, as well as perceptions of influence on the smoking behaviour, attitude, or knowledge. Specific questions were added to the monitoring data collected at 12-weeks (see Additional File 3).

Data analysis

Thematic analysis, a recognised method to identify, analyse, organise, describe, and report themes found within qualitative data, was used (44). Data were coded in six phases: familiarisation with data, generating initial codes, searching for themes among codes, reviewing themes, defining and naming themes through the production of a 'coding frame', and producing the final analyses through the application of the coding frame to available data (44). The use of a coding frame allows for the organisation of codes, to encourage trustworthiness of the data though each phase of the thematic analyses (45). NVIVO version 12 software was used to organise data into themes and nodes.

Three researchers (CD, KOS & EB) independently read all transcripts. Rigorous line-by–line coding was applied, with a focus on experiential claims and concerns. Data patterns were clustered into a thematic structure to identify and categorise major themes and sub-themes. Data saturation was achieved when no new codes or themes emerged within the analyses (46). Any differences in interpretation were resolved through discussion. A fourth independent researcher (JI) with qualitative expertise, reviewed the coding frame and applied it to approximately 10% of transcripts, improving analytical triangulation (47). Transcripts were not returned to participants. Social network data were analysed in Excel separately, to assess the number (%) of people in each participant' network and their mean (SD) age.

Results

Of 50 women invited, 21 accepted the invitation to interview across the four pilot trial waves; one scheduled participant did not attend; the remainder were not available during the interview timeframe (one to two weeks post final programme session). All CFs (N=8) were also interviewed. A total of 26 interviews were conducted: Wave 1: 4, (2 CFs); Wave 2: 8, (2 CFs); Wave 3: 7 (includes two separate CF interviews); Wave 4: 7 (2 CFs).

Figure 1 displays the overall coding frame for the qualitative results, categorised into a) 'Programme level' and b) 'Trial level' results following the MRC process evaluation framework.

Category I. Programme level results

Two main themes were identified under this category: NRT and group support.

Theme 1. Nicotine Replacement Therapy (NRT)

Subtheme 1.1. Cost of and access to NRT

In Ireland, patients entitled to the General Medical Scheme (GMS) are eligible for low or no cost prescriptions (48), while non-GMS 'private' patients typically pay directly for NRT. In the current trial the cost of NRT for non-GMS patients was covered by the Irish Cancer Society. This was noted and appreciated by the participants.

W4–P049: *It was great [free NRT], yeah, yeah, I found it fantastic. It was great to get it.*

Participants who were GMS-entitled were required to obtain an NRT prescription before it could be dispensed without charge. In some circumstances this created a problem because of a lack of available general practitioner (GP) appointments and could also result in the participant feeling uncomfortable when engaging with the dispensing pharmacy.

W4–CF 2: *… one of the ladies said sure 'I can't even get an appointment; it takes 3 weeks to get an appointment'…*

W4–CF 1: *And then when the pharmacists confronted the ladies about the prescription they kind of were uncomfortable that they felt em they were being put under a bit of pressure to get the prescription off their doctor and they were stressing over it. One girl was very stressed about it, she was actually nearly crying here one night because she said she was left sitting for over half an hour in the pharmacy and… She felt like she was under complement to them, you can't have that when you're going through a programme like this, it's just too stressful.*

Subtheme 1.2. Views, beliefs, and opinions about NRT

Despite positive feedback from participants who were able to access NRT for free, there were negative views about the side effects of NRT, including taste and irritability relating to fluctuations of mood.

W3–P0005: *I never felt sick from cigarettes. It's (the patch) making me sick and sometimes I'm afraid that when I'm putting the patch on I'm scared that this is going to make me sick.*

The CFs understood that women may have concerns about NRT side effects either from previous personal experience or from listening to friends' and family members' experiences. Participants also expressed concern about the potential for NRT dependence, and the concept of swapping one 'addiction' for another while not addressing the habitual aspects of smoking:

W4–P065: *Yeah, and I'm still having to use the nicotine replacement there now and I'm still dependent on that. I'd had a big worry about getting addicted to this (inhaler)…I reach for it, just like I used to reach for a cig.*

Subtheme 1.3. Role of the community pharmacist

A key aspect of the WCQ2 trial was to bring clarification on NRT and its role in smoking cessation. To this end, efforts were made in preparatory phases to identify one local community pharmacy in each study area willing to dispense and provide support to the women on their quit attempts.

W1–P0007*: You see the pharmacist coming in like giving an account of what everything does and how you come off it and how you cut down and all like that would be a big help. Yeah, he was very good, his attitude was really good, and he couldn't have been more helpful like do you know. So that was another support there which was really good.*

The community pharmacists involved were going beyond traditional roles of dispensary pharmacy and providing additional support to the women when they presented at the pharmacy for their NRT. During the trial, some CFs actively encouraged participants to link with pharmacists if they were struggling with their quit attempt or lulls in motivation.

W2–CF1: *….they had their moments and they'd arrive in the door to him…And he'd [pharmacist] a little room to the side and he'd take them in and talk it through with them.*

Pharmacists were providing participants with additional brief interventions that may have augmented the group sessions. However, not all community pharmacists were that supportive. Pharmacists were invited to attend a group session to explain NRT, however, not all were willing to do this.

W4–CF2- *No the pharmacist didn't come in because they couldn't, they didn't want to stand up and talk in front of people.*

Theme 2. Group Support and Community Facilitators

Subtheme 2.1. Positive effects of peer support – modelling behaviours for self-efficacy

Participants noted the positive aspect of role-modelling in peer support, which demonstrated that stopping smoking was possible.

W3–P0005: *Going to the meetings…you're more aware of where you were smoking, who was around you…and then by listening to the other people, how they did it, you pick up all the little knick knacks like you know.*

The ability to relate and to recognise oneself within a group is a core tenet of why group support works. Trust and compatibility underpin this and the related concept of learning from others.

W2–P0041: *Well, I found when I came first that everybody was the same as me…You only just felt we're all here together on the same wavelength…. Normally when I give up the cigarettes, I feel that somebody*

has after gone from my life, I'm after losing a friend, I'd be pining but this time I says, 'no I'm not losing a friend'. So, something worked in the head.

Participants' spoke of group support in terms of building capacity by increasing their skills, self-efficacy, and support for maintaining abstinence. The group support they received strengthened and reinforced their intentions to cease or decrease smoking. Participants often provided informational support to one another, offering advice and suggestions about smoking cessation strategies through an informal exchange process.

W1-P0040: *…that lady she taught me one thing that I didn't know, and I taught her something that she wouldn't have known so that's the way that it went around in the meetings, we all found out something different to help us and if one fell off the wagon we'd turn around and say, 'don't worry about it'.*

Subtheme 2.2. Peer teaching, learning and potential for wider message dissemination

Participants reflected that their relationships with members of the group became a part of their motivation to quit:

W3-P0003: *I feel like if I went back smoking I'd be letting them down… it's not about letting myself down, it's about letting them down.*

Through the shared experience, participants demonstrated empathy towards one another. This went deeper than the standard 'common bond in common disease', as outlined here:

W3–CF1: *…it became a nice comfortable space to be in and I think that's what encouraged them to come back. Yes, and for the weeks where they were feeling a bit vulnerable and a bit low and a bit judgemental and self-berating, the other women in the group expressed their encouragement and compassion.*

Related to this was the potential for broader smoking prevention and cessation message dissemination via the social networks of women in the trial. Twenty-four women in the intervention arm provided social networking data and between them made a total of 93 nominations, an average of 3.9 nominations for each WCQ participant, which shows potential for message diffusion. The actual extent of message diffusion was extremely high at 97% (n=90), hence trial participants were speaking to people in their network about the programme (see Additional File 3). Finally, perception of impact was noted in nearly two thirds (61.1%, n=55) of the people spoken to.

Subtheme 2.3. Importance of non-judgemental interactions

Participants felt the support group was a non-judgmental environment where they felt understood, in contrast to attitudes some had encountered outside from both loved ones and healthcare professionals

alike.

W2-P0026: *…because I think they understood what you were going through you know what I mean, people at home were great and they were supportive but they thinking after a day or two you should be over it you know whereas this they knew what you were going through you know so we kind of all went through it together.*

Most participants expressed that the group sessions were a very supportive, encouraging environment that helped motivate them to persist with their quit attempt.

W1-P0004: *do you know, it's a long-term thing, …it's still one day at a time ok but I feel like there's a spell broken, that's the only way I can explain it, that smoking, or addiction is a spell, it's like being in a spell and that's broken, which is huge.*

Subtheme 2.4. Trust and confidentiality

The trust that was built amongst group members facilitated feeling psychologically safe enough to be vulnerable and honest within a group setting. A sense of mutual trust among group members increases the effectiveness of a group (49).

W4–P010: *We were quite an open group. The kind of type of women just wearing our life on our sleeve and just say what we had to say.*

Women reported the freedom to discuss their general stress in their lives and the stress experienced vis-a-vis making a quit attempt.

W2-P0011: *Yeah I didn't hide it because it was so private. I wasn't going to lie and say everything was great because we all had a good rant every now and again. ….somebody was going through the same, they were really close to tears, and just to see that and go, "right I'm not cracking up, I'm not losing my mind. It's normal".*

Category II. Trial level results

This category of results comprised two main themes: data collection methods and measures, and fidelity.

Theme 3. Data collection methods and measures

Subtheme 3.1. Provision of a salivary sample.

Biochemical verification of smoking status is expected in smoking cessation trials to evaluate intervention effectiveness. We asked participants their experience of providing a salivary sample for this biochemical validation. Some participants found the process acceptable.

W1–P0040: *That was grand, but it got stuck in your mouth trying to get it wet. Me mouth was lovely and wet before it went in and then all of a sudden it just dried up and I wasn't sure whether it was wet enough or not. No, it wasn't a problem because it has to be studied.*

However, others reported that the process of providing the salivary sample was very challenging.

W4–P010: *It was awful. It took me ages to get a bit [of saliva]. It [the cotton swab] was very big for my mouth.*

Subtheme 3.2. Literacy levels.

Literacy levels among participants were explored both in relation to the WCQ2 participant intervention booklet, a standard part of the programme, and paperwork associated with the trial.

W3-P0013: *The only thing that I would get you to look into is that with the writing. Too much papers, too much writing in. And I think like that for people that want to give up the cigarettes but can't write and you might get some that can't read and it's embarrassing for them and that would turn them off then in going to the sessions. That's the main thing.*

W1–P0040: *I can't spell for diamonds, so I found it difficult if I was to write in it. One question you could put at the start [is to ask] if you have a problem filling out the forms or if you need help to complete or break down the [writing], we have no problem doing that.*

The CFs were largely experienced in delivering the programme in SED communities so they were familiar and sensitive to low literacy. One CF had a background as a literacy tutor in a different role and she shared her insights:

W3–CF 2: *You can see that straight off when you go into a room because there's the tell-tale signs, people are forgetting their glasses and forgetting their journals the second week…. when they think of the 'We Can Quit' programme they don't realise about the journal and that can be very off-putting when a person comes in and they're handed a journal. They can see that it's like a workbook as well and that there's writing to be done. And often like as we say the first time at any class, we always stress that you know this journal is yours and it's not for us to see and what you do in it is your business…*

Subtheme 3.3. Use of repeated measures.

Questionnaire data were collected at baseline, and at 12-weeks and 6-months post-intervention. Women reported satisfactory understanding of the necessity for multiple data collection timepoints.

W4 – P049: *Not at all, no, no with the help that I was after receiving I was more than willing, more than willing whatever I had to what I had to do to answer the questions. It's payback.*

This willingness extended to providing a biological sample on more than one occasion, with one woman stating:

W3 – P004: *I wasn't mad about giving the sample again because my mouth gets very dry but the girl [research assistant] explained why I needed to do it again – so I did it.*

Theme 4. Fidelity

Subtheme 4.1. Tailoring sessions to checklist instead of intervention manual

Fidelity to the intervention manual was assessed by self-report methods through a checklist of intervention sessional components, completed after each session by the CFs (27). Generally, CFs gave a positive reaction to the fidelity checklist:

W1–CF 1: *The evaluation is good because I was using that and then I'd turn it into my own little thing reminders you know the evaluating at the end of every group.*

There was a sense from the CFs that the use of the fidelity checklist went further than just a behavioural prompt for sessional content delivery and was discussed in terms of conscious efforts to change delivery of sessions.

W2–CF 2: *You kind of are watching a lot more…..because we had to chart everything and you were more inclined to try and stay on course. Sometimes in a group you go in with a lesson plan, but it goes totally out the window because somebody starts to talk about something else and it takes off on its own. But this time around, I made much more of an effort to stick to the plan.*

One CF noted that for her the presence of the fidelity assessment processes meant that she felt she was being 'watched' by the research team.

W2–CF 1: *I was following because I did feel you know our own diary, our community diary that was very much a kind of a big brother watching that you need to do those things.*

Subtheme 4.2. Acceptability of direct or indirect methods of fidelity assessment

Hypothetical scenarios were presented to all interviewees regarding alternative fidelity assessment methods. These included direct observational methods (e.g., having a researcher present in the room

during group sessions) or indirect methods (e.g., sessions audio recorded and assessed at a later stage by the research team). There were some concerns raised by CFs that indirect observational recording could threaten the privacy of session, and whether an audio recording could interfere with the dynamic of the session:

W2–CF 2: *I wouldn't say record it because it's personal to the women taking part. I wouldn't mind them watching and that, but I wouldn't fancy it being recorded.*

W2–CF 1: *Yeah, the watching wouldn't bother me, but I think it would change the dynamic of the room if it was recorded.*

There was little concern about having an independent observer changing the group dynamic from other CFs.

W3–CF 2: *I certainly wouldn't have an issue; I can understand what the research is for. I wouldn't have an issue. You would have an earful with this group anyway! But em I don't think that would have stopped anybody [from speaking].*

This was underscored by one participant who recalled that during one session the community pharmacist was present and that had no impact on the direction or tone of the session.

W4–P00027: *No because I remember when the pharmacy guy came in he was there for one session and nobody batted an eyelid. It was just like he was there on the sidelines before he went off speaking. So no, it was fine.*

The issue of prior knowledge and consent relating to fidelity measurement was echoed amongst programme participants.

W2–P0006: *I wouldn't have an issue with that as long as you were giving advance notice and there was real clarity around it.*

This pragmatic, democratic and altruistic approach to fidelity was also shared amongst women in terms of indirect audio recordings. Alongside this an additional key issue around the confidentiality and safe keeping of recordings came into play.

W2–P0001: *So long as it was falling into the right hands and it was for research and was going to help people and maybe make the course better to help other people give up the cigarettes then [I've] no problem with it. It would just show what is discussed in the group and the recordings would show that the discussions that take place are invaluable.*

This altruistic consideration recognised fidelity as a part of research evaluation of the programme itself.

W2–P0015: *I don't think so, no. Do you know it's for research like. It's brilliant like. Obviously other women are going to you know gain from what we've done, so if someone could save someone do you know it's*

worth it like?

Discussion

The key findings of this process evaluation focused on programme and trial level factors. Facilitative factors included peer-modelling, a non-judgemental environment, and CFs supportive role of group support. For some participants provision of a saliva sample proved challenging. Participants valued free NRT as helpful for cessation, although some concerns about NRT side effects were expressed. Community pharmacists provided important guidance relating to NRT and additional support between programme meetings. Low literacy amongst some participants was a barrier for engagement with both programme- and trial-related materials. Hypothetical scenarios of direct or indirect observational fidelity assessment for potential use in future DT were acceptable.

Peer support can foster a sense of community and promote continued abstinence from smoking. Support groups allow individuals to learn from each other, especially when abstinence is difficult (50). A non-judgemental and empathetic ethos tends to be a core component of addiction recovery models (51). Attitudes of others are a major factor in determining programme engagement (52). This ethos was a facilitative factor for WCQ2 engagement. Participants in the current trial found these groups helpful including: feeling accountable to others, strengthening motivation, reinforcing what had been learned, learning strategies that helped others successfully quit, and allowing those who quit to share their experience and be a role model for others.

Many smoking cessation interventions include some social support element. Recent public health guidelines in the UK advocate its use (53). Social support is frequently considered a predictive variable in community health surveys and behavioural change interventions (54). There are different types of social support. Firstly, structural support is the presence of family/ friends/social networks within a person's life. Secondly, functional support is the quality of those relationships. This includes emotional support (empathetic listening), and instrumental support (e.g., practical assistance/information provision. A third type of "support" (or its opposite) is the smoking behaviour of close others in the persons environment (e.g., partners, friends, and colleague's). These three aspects of social support are closely interrelated and were reported as present in WCQ2. Several community-based health behaviour change interventions have included the support of a 'buddy' from within the participants existing social network. Studies have found having such a buddy is correlated with smoking cessation (55, 56). Although WCQ2 did not formally ask participants to select a 'buddy', participants reflected that some of their motivation was a desire not let down other members of the group. This type of camaraderie is typically seen in groups that have known each other a long time (57), however, it was reported as present in WCQ2 during a short 12-week period. Stress is an important confounding factor that increases risk for relapse (58). Lower social support can lead to increased smoking intensity and lower cessation and abstinence (59). Social support can affect stress levels after cessation, especially within SED cohorts (60). Findings from the limited social network analyses suggest that participants in the programme could act as potential promotors of a smoke free culture amongst their own networks and broader communities. However, we did not explore whether the

impact of this message diffusion was positive or negative. Furthermore, perceptions of impact on the nominated participants are only from the programme participants. These aspects could be explored further in a DT.

As NRT for harm reduction is often obtained over the counter, without prescription (61), it appears that income and the cost of NRT are factors that affect its use (62). Previous studies have suggested that NRT use may increase if smokers are provided with free products (62, 63) and have the opportunity to participate in programmes wherein smokers can find the NRT product most effective for them (64). These strategies may reduce the social inequalities found in the NRT usage (65). Importantly the much-cited barrier of 'NRT cost' was removed from participants in this study as the cost was borne by the charity responsible for developing the programme and not by the HSE. However, the difference pathways to access free NRT between GMS and non-GMS participants in the same arm of the trial is an important contextual factor. A key solution to the problem of equal access to NRT lies in the bigger question of the two-tiered system within Ireland, which goes beyond the scope of the current project. The implementation of Slaintecare (66), a whole of Government approach to universalisation of healthcare provision in Ireland will promote equality and endeavour to remedy structural, administrative and financial barriers for women from SED communities and other marginalised groups.

Participants' concerns about potential side effects of NRT are in line with previous findings (67), and may act as a barrier towards its use in the long-term, or incorrect or under-use (68, 69). Concerns about becoming 'addicted' to NRT and about the health consequences associated with NRT are commonly held beliefs by many smokers and ex-smokers (70, 71). This is despite the fact that the risk of becoming addicted to medicinal nicotine is very rare (72, 73) and are heavily outweighed by smoking risks. While NRT advice and guidance is a formal part of the WCQ programme, it would be important to standardise the scheduling of pharmacists' attendance during the relevant programme session (74). This will require an expansion of the role of the pharmacist beyond what was originally envisaged in the pilot trial in sustaining and promoting cessation between programme group meetings. This was not the case in one of the four trial Waves, in which pharmacist interactions with women were less than ideal. Nevertheless, in the other three Waves the women spoke highly of the pharmacists and indeed would often present to the pharmacist between programme sessions for additional support. Future research should comprehensively map and identify the aspects of these interactions, and enhance the intervention at the pharmacist level in a DT.

RCTs are considered the gold standard in clinical research. However, RCT participation may be challenging. Participants who are managing burdens associated with their behaviours (e.g., respiratory problems associated with smoking) could face additional burdens related to trial participation, such as trial research visits or supplementary procedures (some of which may be invasive e.g., provision of a salivary sample) and completion of trial questionnaires. Such tasks may deter trial participation.

Capturing smokers' experiences within cessation trials is complex, not only in terms of the multiplicity of trial design features, but also the relapsing and remitting nature of the behaviour. Therefore, gathering

repeated information over time is essential for understanding the behaviours under investigation (e.g., smoking and quitting), but also to accurately assess the intervention's effects that are designed to change those behaviours (e.g., a programme like WCQ).

We found that it is both feasible and acceptable to collect repeated measures as they related to key trial processes which included questionnaire assessments and biological sampling over a 12-week period. Even though trial measurement continued beyond this timepoint the qualitative interviews were coupled with the end of intervention delivery, therefore, we do not know how participants felt after six months. However, retention rates were almost as good at six months as they were at the end of programme delivery (at 12-weeks: 55.4%; at 6-months: 47.7%) (30).

One in six Irish adults has problems reading (75). The relationship between literacy and participation in clinical research is poorly understood (76). Shame and reluctance to disclose reading difficulties often accompany low literacy status (77), and less-literate people may decline to engage in research activities that might expose their poor literacy skills. Investigators may unknowingly facilitate this selection bias. In the WCQ2 trial, efforts were made to explain complex terminology in layperson's language in the consent form and the participant information leaflet (PIL), but a necessary balance was struck to include sufficient detail to comply with legislation such as General Data Protection Regulations (78) related to explicit informed consent and research transparency. This presents both an ethical and a practical challenge for any community-based trial that includes participants with low or no literacy ability. A future DT could explore Study Within A Trial (SWAT) strategies to improve processes relating to informed consent and also how best to communicate complex health related information as it pertains to smoking cessation.

Intervention fidelity is the extent to which an intervention is implemented as described in an intervention manual or programme (79). The strategies and techniques to monitor intervention fidelity ae often omitted or poorly described within trials of complex health behaviour change interventions (78–82). Problems can arise regarding fidelity at several levels; for example, several different people may deliver the intervention, the settings in which the intervention is delivered are dissimilar, or the intervention protocol as described in the manual or trial documents is vague. Delivery of a complex behavioural change intervention at community level is a significant challenge but there are strategies to capture and report these dynamics which should be included in publications (83). This is important because of the influence that fidelity has on trial outcomes; principally, in DT's if non-significant results are found, it is difficult to establish if the results are because the intervention was ineffective or whether other factors are responsible(84). Furthermore, data on the knowledge, practice and attitudes of stakeholders involved in trials of complex interventions towards fidelity measures and techniques remains scarce. In the current study, specific questions about the acceptability of alternative observational methods of intervention fidelity provided attitudinal insights. Findings identified a degree of awareness of the potential benefits of intervention fidelity to participants and which in turn could be helpful to researchers with interest in trials of complex interventions.

This study had a number of limitations including recruitment that resulted in a self-selecting sample of smokers; the majority of those that were interviewed had quit smoking thus may have been unrepresentative, in that women who engaged, but saw themselves failing to maintain a quit attempt, may not have volunteered to be interviewed. In addition, we did not interview women at six-months follow-up when they had a greater period to reflect on their experience. A longer follow-up, however, could have introduced retrospective bias. The researcher, who conducted the interviewers, was known to participants throughout the trial (e.g., took informed consent, conducted baseline assessments), which may have introduced some bias. There was some evidence of variation in the fidelity of the delivery of the intervention as it related to the support from the community pharmacist (e.g., Wave 4).

The study also had a number of strengths including the application of the MRC process evaluation guidance (31) within a community based smoking cessation trial.

Recently, the WHO has recognised the urgency of addressing tobacco use in women and the need for tailored interventions targeting specific groups of women(85). The study focused on gaining the views of a population that is considered ‘hard to reach’ e.g., women from disadvantaged areas. In-depth qualitative interviews took place with both those who received the intervention and those who delivered it, eliciting views on both the programme itself and trial processes. This comprehensive approach will prove to be important should the programme require updating and/or in future research should the study go forward to a DT. The trial utilised COREQ guidelines which are the standardised reporting framework to improve transparency and clarity of reporting in qualitative research (43).

Conclusions

Overall, both programme and trial-related processes were deemed feasible and acceptable. Provision of free NRT was welcomed by participants, although some barriers remain for GMS-entitled women who still required a GP’s prescription to access the medication without charge. The role of the community pharmacist should be examined and mapped to understand interactions with participants between programme meetings. The potential expansion of the role of the community pharmacist should be considered. A future DT will need to address the low literacy levels of women from SED groups both in terms of programme related materials and trial related materials such as participant consent forms, information leaflets and questionnaire measures.

Abbreviations

SED: socioeconomically disadvantaged population

WHO: World Health Organization

RCT: randomised controlled trial

NRT: nicotine replacement therapy

WCQ2: We Can Quit2

WCQ: We Can Quit

CFs: community facilitators

DT: definitive trial

MRC: Medical Research Council

HSE: Health Service Executive

GMS: General Medical Scheme

GP: general practitioner

Declarations

Ethics approval and consent to participate.

The We Can Quit2 study obtained ethics approval from the School of Medicine Research Ethics Committee, Trinity College Dublin, in 03/05/2017 (Reference number: 20170404). Participants gave informed consent. All research procedures have been performed in accordance with the Declaration of Helsinki.

Consent for publication.

Not applicable.

Availability of data and materials.

The pooled anonymised quantitative data analysed during the current study are available from the corresponding author on reasonable request. The qualitative data are not publicly available to protect the privacy and confidentiality of study participants.

Competing interests.

CBH reports grants from HRB and Enterprise Ireland during the conduct of the study. CD reports grants from HRB during the conduct of the study. All the remaining authors do not have any competing interests.

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Authors' contributions.

CBH as PI, and CD, JV, LB and ND as co-PIs, acquired funding for the WCQ2 trial. CBH directed all study components. CD led the design and analysis of the process evaluation with significant input from FD, PW, JV, KL, CBH in conceptualisation, and EB, and KOS in data analysis and validation. EB carried out the interviews. NO'C, CR and AB, coordinated the implementation. The manuscript was drafted by CD, SC and CBH. Tables and figures were prepared by SC who provided editorial assistance. All authors contributed to content and approved the final manuscript.

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Figures

Figure 1

Coding frame for the qualitative results, categorised into **(a)** 'Programme level' and **(b)** 'Trial level' results following the MRC process evaluation framework.

Medical Research Council Process Evaluation Framework:

1 Context (e.g., contextual factors that shape theories of how the intervention works; contextual factors that affect (and may be affected by) implementation, intervention mechanism and outcomes; causal mechanism present within the context which act to sustain the status quo or potentiate effects)).

2 Implementation (e.g., implementation process (how delivery is achieved; training, resources, etc); what is delivered – fidelity, dose, adaptations, reach).

3 Mechanism of impact (e.g., participant responses to and interactions with the intervention; mediators; unexpected pathways and consequences.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile1.docx
- Additionalfile2.docx
- Additionalfile3.docx
- WCQCOREQChecklist01.11.2021.pdf