A process evaluation of "We Can Quit"

Title: 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 (346/350)

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. This includes group-based support delivered by trained lay local community facilitators (CFs) and free nicotine replacement therapy (NRT). The intervention was pilot tested in a cluster randomised controlled trial, 'We Can Quit 2'. This paper reports on the WCQ2 process evaluation which assessed feasibility and acceptability of the programme and trial processes.

Methods: Embedded qualitative design using the UK Medical Research Council's process evaluation framework. Semi-structured interviews with trial participants (N=21) and CFs (N=8). Thematic analysis was utilised.

Results: Peer-modelling, a non-judgemental environment, CFs facilitation of group support were viewed as acceptable programme related factors. Some participants expressed concerns about NRT side effects. Provision of free NRT was welcomed and accepted by participants, although structural barriers made access challenging. Pharmacists took on a role that became larger than originally envisaged – and the majority provided additional support to women in their quit attempts between group meetings which augmented and supplemented the intervention sessions provided by the CFs. Participants reported good acceptance of repeated measures for data collection, but mixed acceptability of provision of saliva samples. Low literacy affected the feasibility of some women to fully engage with programme and trial-related materials. This was despite efforts made by intervention developers and the

trial team to make materials (e.g., participant intervention booklet; consent forms and participant information leaflets) accessible while also meeting requirements under 2018 European General Data Protection Regulation legislation. Hypothetical scenarios of direct (e.g., researcher present during programme delivery) and indirect (e.g., audio recordings of programme sessions) observational fidelity assessments for a future definitive trial (DT) were acceptable.

Conclusions: Intervention and trial-related processes were generally feasible and acceptable to participants and CFs. Any future DT will need to take further steps to mitigate structural barriers to accessing free NRT; and the established problem of low literacy and low educational attainment in SED areas, while continuing to comply within the contemporary legislative research environment.

Keywords: Smoking cessation, behavioural intervention, NRT, deprivation, women, trials, qualitative, process evaluation.

Trial registration: WCQ2 pilot trial (ISRCTN registration 74721694)

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). Social determinants that exacerbate 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 greater 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 for 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). Findings from other studies have shown that the use of nicotine replacement therapy (NRT) increases the rate of quitting by 50% to 60%, regardless of setting (23), and can help to prevent smoking relapse (24). However, 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. It set out 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 (SEM) (28) and developed using a community-based participatory research approach (29). The detailed trial methodology and 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 UK Medical Research Council (MRC)(31), provides a framework for assessing an intervention's implementation, the identification of contextual factors and proposed mechanisms for change. It is considered an essential part of designing and testing complex interventions and complements earlier UK MRC guidance (33). Hence, a qualitative, mixed-method process evaluation was embedded into the WCQ2 trial, following UK MRC specific guidance(31). To our knowledge few smoking cessation feasibility trials have applied UK 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).

In this paper, we expand upon this important area and take an in-depth approach investigating programme factors (group based delivery, role of community facilitators, free NRT) while also taking into account how the intervention interacted with the context of the participants (women from SED with low literacy) and the context in which the trial was implemented (General Data Protection Regulations (GDPR) 2018(37) legislation relating to trial documentation).

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 (38–41). 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 (39). This aspect of the trial embraces a qualitative research design, using face-to-face individual and paired interviews. 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 (42). Stakeholder interviews are a common method of inquiry as outlined by the UK 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

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 combination NRT (43)

without charge for all women (e.g., patches, with either inhalator, gum, lozenges or spray). The WCQ intervention also included advice from community pharmacists to support NRT use (e.g., titration of NRT amounts). In Ireland, patients entitled to the General Medical Scheme (GMS) are eligible for low or no cost prescriptions(44), while non-GMS 'private' patients typically pay directly for NRT. CF 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 an intervention booklet which included fact sheets, activity worksheets, a handheld NRT record, and signposting information. They were invited to keep a smoking journal to use as a personal space for reflections from the first session to increase their understanding of their smoking behaviour.

Selection of participants

A purposive sampling procedure was employed, targeting key stakeholders involved in the trial. The focus of recruitment was to identify and select information-rich cases (45) 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, including self-reported smoking behaviours at baseline are shown in Table 1.

Table 1. Baseline socio-demographic and smoking characteristics of We Can Quit intervention participants who were interviewed and outcome assessment at 12-week follow-up interview (N=21)

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)
General Medical Scheme (GMS) entitled patients or General Practitioner 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	
Not at all determined	0
Quite determined	6 (28.6)
Very / Extremely determined	15 (71.4)
We Can Quit intervention delivery	
Attendance at sessions	
Between 1 and 8 sessions	8 (38)
Between 9 and 12 sessions	13 (62)
Used Nicotine Replacement Therapy 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)

188 * Three participants did not give any information on NRT use.
189 ** Corroborated by saliva tests.
190 ^ General Medical Scheme (GMS) entitled patients are eligible to access primary care services free of
191 charge and are eligible for low or no cost prescriptions. Those patients with a General Practitioner
192 (GP) card are eligible to see their GP free of charge.
193

Description of Community Facilitators (CFs)

The CFs selected by the WCQ delivery partners, belonged to or worked in the community where they delivered the training. Most (seven out of eight) were ex-smokers. Three were full time professionals across areas such as family support, local development programmes (e.g., a community worker role) and/or adult education. Their time spent working on the WCQ programme was covered by their employer.

All CFs were trained to the National Standard in Smoking Cessation(46) and CFs in Wave 4 were also trained in group facilitation skills (comprising two days of training). Facilitators in Wave 1 had previous experience in delivering the original WCQ pilot programme in a different community setting. For Waves 2, 3 and 4, it was their first time delivering the programme. All CFs were women.

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. A participant information leaflet (PIL) was provided to participants. Informed written consent was obtained prior to commencing interviews and participation was voluntary. Efforts were made to explain complex terminology in layperson's language in the consent form and the PIL by also engaging with the National Adult Literacy Agency (NALA)(47). A necessary balance was needed in order to include sufficient detail to comply with legislation such as GDPR(37). The Research Assistant (EB) verbally explained all trial processes to participants to maximise informed consent. The PIL and consent forms were given to each participant at least 24 hours before signing, affording participants time to review.

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) (48).

Data analysis

Thematic analysis, a recognised method to identify, analyse, organise, describe, and report themes found within qualitative data, was used (49). 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 (49). The use of a coding frame allows for the organisation of codes, to encourage trustworthiness of the data through each phase of thematic analyses (50). 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 (51). 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 (52). Transcripts were not returned to participants.

Results

Of 50 women invited, 21 were interviewed (this corresponded to a total of 3, 7, 5 and 6 women from Waves 1 to 4 respectively; 41% response rate) within the timeframe (one to two weeks post final programme session). The full cohort of CFs were interviewed, two in each of the four intervention sites, resulting in a total of eight CFs interviews.

Figure 1 displays the overall coding frame for the qualitative results, categorised into a) 'Programme level' and b) 'Trial level' results following the UK MRC process evaluation framework(31).

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 the WCQ2 trial, the cost of NRT for non-GMS patients was covered by the Irish Cancer Society. This was seen as acceptable and appreciated by participants.

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

However, GMS-entitled participants were required to obtain an NRT prescription before it could be dispensed without charge. In some circumstances, this created a feasibility 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.*

Subtheme 1.2. Views, beliefs, and opinions about NRT

Some participants expressed concerns about using NRT. Some concerns were associated with views that NRT can make the user feel ill.

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.*

Other concerns related to its perceived potential for dependence.

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 of the four study areas willing to dispense and provide information and 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.*

However, some pharmacists were going beyond traditional roles of dispensary pharmacy and were providing participants with additional brief interventions that may have augmented group sessions when they presented at the pharmacy for their NRT. It also became apparent that some CFs actively encouraged participants to link with pharmacists if they were struggling with their quit attempt or lulls in motivation between group meetings. This was seen as acceptable by participants.

W2–CF 1: ….*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. The chat with the pharmacist really kept them going in their quit attempts. They'd arrive down to him sometimes in a panic.*

However, not all pharmacists were as supportive. For example, an optional component of the programme included CFs inviting pharmacists to attend a group session to explain NRT, however, not all were available or willing to do this.

W4–CF 2: *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 were very accepting of role-modelling behaviours which demonstrated that stopping smoking was possible which featured as part of the group sessions.

> 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 embracing and accepting 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.

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

In practice, 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… 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'.*

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 shared experience, participants demonstrated empathy, which went deeper than the standard 'common bond in common disease', as outlined here:

> W3–CF 1: *…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 judge[d] and self-berating, the other women in the group expressed their encouragement and compassion.*

Subtheme 2.3. Importance of non-judgemental interactions

Participants described the support group environment as being an accepting non-judgmental one where they felt understood. This was in contrast to attitudes some had encountered from loved ones.

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

Most participants expressed that group sessions enhanced the feasibility of them persisting with their quit attempt:

> W1-P0004: *… 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

A sense of trust was built up to such an acceptable level that participants reported feeling psychologically safe enough to be vulnerable and honest.

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 freedom to discuss their general life stresses 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. Feasibility and acceptability of data collection methods and measures

Subtheme 3.1. Provision of a salivary sample.

Biochemical verification of smoking status is standard in smoking cessation trials to evaluate intervention effectiveness. We asked participants about their experience of providing a salivary sample. 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 not feasible for them.

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 very experienced in delivering community education programmes 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…. they don't realise about the journal and that can be very off-putting when a person… They can see that it's like a workbook as well and that there's writing to be done. And often… we always stress that 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.

As a part of the trial processes, questionnaire data were collected at baseline, and at 12-weeks and six-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…whatever I had to what I had to do to answer the questions. It's payback.*

There was mixed acceptability relating to the process of providing a biological sample on more than one occasion, although they agreed to it, 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 trial 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 were accepting of this process and 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.*

However, there was a sense from the CFs that their 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… 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 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., audio recording of sessions and assessed at a later stage by the research team). There were some concerns relating to the acceptability of these proposed processes as a perceived threat to session privacy, 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.*

However, there were no concerns 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 don't think that would have stopped anybody [from speaking].*

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 accepting 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.*

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

Discussion

The aim of this process evaluation was to examine the feasibility and acceptability of programme and trial related factors. Acceptable factors of the delivery of the intervention included peer-modelling, a non-judgemental environment, and CFs positive facilitation of group support. For some participants, provision of a saliva sample proved challenging. Participants valued free NRT as a facilitative mechanism for cessation, although some concerns about NRT side effects were expressed. Community pharmacists provided important guidance relating to NRT and additional support as a mechanism for cessation between programme meetings. The context of low literacy amongst some participants was a challenge for the feasibility of engagement with both intervention, and trial, related materials. Hypothetical scenarios of direct or indirect observational fidelity assessment for potential use in future DT were acceptable.

A key finding from this process evaluation was the importance of social support, with participants noting the value of peer group support. Benefits included: feeling accountable to others, strengthening and reinforcing motivation, learning successful strategies from peers, and allowing those who quit to share their experience and be a role model for others. It is encouraging then, that public health guidelines in the UK advocate for social support to be included in smoking cessation interventions (53). Social support can foster a sense of community and promote continued smoking abstinence, with positive attitudes of others as major factors in determining programme engagement (54). Stress is an important confounding factor that increases risk for relapse(55). Lower social support can lead to increased smoking intensity and lower cessation and abstinence (56). Social support can moderate stress levels after cessation, especially within SED cohorts (57).

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 and acceptable in WCQ2. These are also important factors as mechanisms for change within the theory of SEM (28) which underpins the programme.

Several community-based health behaviour change interventions have included the support of a 'buddy' from within participants' existing social network, and found this to be correlated with smoking cessation (58,59). 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 (60), however, it was reported as present in WCQ2 during a short 12-week period.

Previous studies have suggested that NRT use may increase if smokers are provided with free products and given the opportunity to find the NRT product most effective for them (61,62) (63). These strategies may reduce the social inequalities found in NRT usage (64). Importantly the much-cited barrier of 'NRT cost' was removed from participants in this trial as the cost was borne by the charity responsible for developing the programme and not by the HSE. However, the

different pathways to accessing free NRT between GMS and non-GMS participants in the same arm of the trial is an important contextual factor. GMS participants had to seek a prescription from their GP in advance of the pharmacist dispensing it. In some circumstances, women struggled to get appointments and approached pharmacists to fill the prescription ahead of getting it converted to a GMS prescription. This created embarrassment for these women, especially if the request was refused. This has implications for implementation of this aspect of the intervention. It highlights how this structural issue will need to be pre-empted and resolved for the programme to run more smoothly next time. It is important to note that the key solution to the problem of equal access to NRT lies in the bigger question of the two-tiered health system within Ireland, which goes beyond the scope of the current project.

Participants' expressed concerns about the potential side effects of NRT, which are in line with previous findings (65), and may act as a barrier towards its use in the long-term, or incorrect or under-use (66,67). Concerns about becoming 'addicted' to NRT and about the health consequences associated with NRT are commonly held beliefs by many smokers and ex-smokers (68,69). This is despite the low risk of NRT addiction (70,71) which is heavily outweighed by smoking risks. In three of the four waves women spoke highly of pharmacists and would often present to them between intervention sessions for additional support. Payment in this pilot trial for pharmacists' time related to the dispensing of NRT with their professional guidance around medication usage only. Future DT research should comprehensively map and identify the interactions between participants and pharmacists, and also look at

631 the provision of behavioural support training to participating pharmacists to
632 standardise these interactions.

633

634 RCTs are considered the gold standard in clinical research. However, RCT
635 participation can be challenging. Participants who are managing burdens associated
636 with their behaviours (e.g., respiratory problems associated with smoking) could face
637 additional burdens related to trial participation, such as trial research visits or
638 supplementary procedures (some of which may be invasive e.g., provision of a
639 salivary sample) and completion of trial questionnaires. Gathering repeated
640 information over time is essential for understanding the behaviours under
641 investigation (e.g., smoking and quitting), but also to accurately assess the
642 intervention's effects that are designed to change those behaviours (e.g., a
643 programme like WCQ). Such tasks may deter trial participation. However, we found
644 that it was both feasible and acceptable to collect repeated trial measures including
645 questionnaire assessments and biological sampling over a 12-week period, for most
646 participants. Retention rates were almost as good at six months as they were at the
647 end of programme delivery (at 12-weeks: 55.4%; at 6-months: 47.7%) (30), which
648 would suggest that participants that were retained at the end of programme delivery
649 were happy to continue to provide trial data at 6 months. This is important for
650 implementation of the next phase of the trial in which we will hope to recruit and
651 retain as many participants as possible through each of the data collection
652 timepoints.

653

One in six Irish adults have reading problems (72). The relationship between literacy and participation in clinical research is poorly understood (73). Shame and reluctance to disclose reading difficulties often accompany low literacy status (74), and may result in less literate people declining to engage in research activities that expose their poor literacy skills. Investigators may unknowingly facilitate this selection bias. The intervention materials (e.g., participant booklet, CF resource pack) were co-designed, delivered and adapted by experienced community development workers and health professionals. Programme materials were written and edited by health promotion professionals who were trained in plain English writing by NALA (47). CFs are trained to demonstrate and deliver the core exercises in the programme without paper through interactive group work and props, (e.g., demonstrating a CO monitor). CFs received specific training in providing the first two programme sessions to build rapport with participants and show support in completing processes to take account of literacy needs.

It is now understood that GDPR has raised the bar for explicit informed consent and research transparency (75). While responding and augmenting materials to increase accessibility is not new, in the post-GDPR era of conducting community-based trial research it does present both an ethical and a practical challenge for any trial that includes participants with low or no literacy ability. There are a number of implications arising from this area of the process evaluation that covers both the delivery of the programme, the next steps of a DT and more broadly at policy level. The programme providers (ICS) should review the programme and CF training guidance to further consider the challenges for low literacy participants and identify what additional supports are available in the community to address these. In

addition, a dedicated section in the CF resource pack should be developed with suggestions to pre-empt and overcome these challenges in the programme. A future DT, through a Study Within A Trial (SWAT) could test strategies to improve processes relating to distilling informed consent and also how best to communicate complex health related information as it pertains to smoking cessation. At a policy level, the findings highlight the need to address educational inequality in public education. This structural societal issue can limit the impact of health and wellbeing programmes within particular population groups, e.g., women experiencing multiple socioeconomic disadvantages who also express a desire to stop smoking.

Fidelity to the delivery of a complex behavioural change intervention at community level is a significant challenge (76). The strategies and techniques to monitor intervention fidelity are often omitted or poorly described (37,77–80). This is important because of the influence that fidelity has on trial outcomes (81), and furthermore, data on the attitudes of trial participants towards fidelity measures remains scarce. In the current study, findings indicated acceptance of fidelity measures for inclusion in the next phase of the trial.

The study had a number of strengths including the application of the UK 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 (82). This 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

703 place with both those who received the intervention and those who delivered it,
704 eliciting views on both the programme itself and trial processes. This comprehensive
705 approach will prove to be important should the programme require updating and/or in
706 future research should the study go forward to a DT. The trial utilised COREQ
707 guidelines which are the standardised reporting framework to improve transparency
708 and clarity of reporting in qualitative research (48).
709

710 This study also had a number of limitations. Recruitment resulted in a self-selecting
711 sample of smokers. The majority of participants that were interviewed had quit
712 smoking and may have been unrepresentative; women who engaged, but saw
713 themselves failing to maintain a quit attempt, may not have volunteered to be
714 interviewed. In addition, we did not interview women at six-months follow-up which
715 would have allowed for a greater period to reflect on their experience. A longer
716 follow-up, however, could have introduced retrospective recall bias. The researcher,
717 who conducted the interviews, was known to participants throughout the trial (e.g.,
718 took informed consent, conducted baseline assessments), which may have
719 introduced some bias. There was some evidence of variation in the fidelity of the
720 delivery of the intervention as it related to the support from the community
721 pharmacist (e.g., Wave 4). The smoking journals that women kept were not
722 assessed by the research team, as these were presented as confidential spaces in
723 which women could note reflections of their smoking beliefs and behaviours. Even a
724 sample of these journals could have elicited some interesting learnings from women
725 as they navigated the programme and their quit attempt.
726

Conclusions

Overall, both intervention 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 group 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 intervention and trial related materials such as the PILs, consent forms and questionnaire measures.

List of 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

UK MRC: UK 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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References

1. World Health Organization. European Tobacco Use. Trends Report 2019 [Internet]. Geneva, Switzerland: WHO; 2019 [cited 2021 Mar 24]. Available from: https://www.euro.who.int/__data/assets/pdf_file/0009/402777/Tobacco-Trends-Report-ENG-WEB.pdf

2. Gallaway MS, Henley SJ, Steele CB, Momin B, Thomas CC, Jamal A, et al. Surveillance for Cancers Associated with Tobacco Use - United States, 2010-2014. Morb Mortal Wkly Rep Surveill Summ Wash DC 2002. 2018 Nov 2;67(12):1–42.

3. Islami F, Torre LA, Jemal A. Global trends of lung cancer mortality and smoking prevalence. Transl Lung Cancer Res. 2015 Aug;4(4):327–38.

4. World Health Organization. Guidelines for implementation of Article 14. Guidelines on demand reduction measures concerning tobacco dependence and cessation. [Internet]. Geneva,

Switzerland: WHO; 2010 [cited 2021 Mar 24]. (WHO Framework Convention on Tobacco Control). Available from: https://www.who.int/fctc/guidelines/adopted/article_14/en/

5. Walsh PM, McDevitt J, Deady S, O'Brien K, Comber H. Cancer inequalities in Ireland by deprivation, urban/rural status and age: a report by the National Cancer Registry. [Internet]. Cork, Ireland: National Cancer Registry; 2016 [cited 2021 Mar 24]. Available from: https://www.ncri.ie/sites/ncri/files/pubs/cancer-inequality-report-summary-2016.pdf

6. Kock L, Brown J, Hiscock R, Tattan-Birch H, Smith C, Shahab L. Individual-level behavioural smoking cessation interventions tailored for disadvantaged socioeconomic position: a systematic review and meta-regression. Lancet Public Health. 2019 Dec 4;4(12):e628–44.

7. Hiscock R, Bauld L, Amos A, Fidler JA, Munafò M. Socioeconomic status and smoking: a review. Ann N Y Acad Sci. 2012 Feb;1248:107–23.

8. Manfredi C, Cho YI, Crittenden KS, Dolecek TA. A path model of smoking cessation in women smokers of low socio-economic status. Health Educ Res. 2007 Oct;22(5):747–56.

9. van Wijk EC, Landais LL, Harting J. Understanding the multitude of barriers that prevent smokers in lower socioeconomic groups from accessing smoking cessation support: A literature review. Prev Med. 2019 Jun;123:143–51.

10. Stewart MJ, Greaves L, Kushner KE, Letourneau NL, Spitzer DL, Boscoe M. Where there is smoke, there is stress: low-income women identify support needs and preferences for smoking reduction. Health Care Women Int. 2011 May;32(5):359–83.

11. Smith PH, Bessette AJ, Weinberger AH, Sheffer CE, McKee SA. Sex/gender differences in smoking cessation: A review. Prev Med. 2016;92:135–40.

12. National Cancer Registry Ireland. Cancer Factsheet: Lung [Internet]. Cork, Ireland: National Cancer Registry; 2018 [cited 2021 Mar 24]. Available from: https://www.ncri.ie/sites/ncri/files/factsheets/Factsheet%20lung.pdf

13. National Cancer Registry Ireland. Cancer in Ireland 1994-2017 with Estimates for 2017-2019: Annual Report of the National Cancer Registry. 2019 Annual Report [Internet]. Cork, Ireland: National Cancer Registry; 2019 [cited 2021 Mar 24]. Available from: https://www.ncri.ie/sites/ncri/files/pubs/NCRI_Annual%20Report2019_03102019.pdf

14. Amos A, Greaves L, Nichter M, Bloch M. Women and tobacco: a call for including gender in tobacco control research, policy and practice. Tob Control. 2012 Mar;21(2):236–43.

15. Graham H, Inskip HM, Francis B, Harman J. Pathways of disadvantage and smoking careers: evidence and policy implications. J Epidemiol Community Health. 2006 Sep;60(Suppl 2):ii7–12.

16. Soulakova JN, Tang CY, Leonardo SA, Taliaferro LA. Motivational Benefits of Social Support and Behavioural Interventions for Smoking Cessation. J Smok Cessat. 2018 Dec;13(4):216–26.

17. Ford P, Clifford A, Gussy K, Gartner C. A systematic review of peer-support programs for smoking cessation in disadvantaged groups. Int J Environ Res Public Health. 2013 Oct 28;10(11):5507–22.

18. Roberts NJ, Kerr SM, Smith SMS. Behavioral interventions associated with smoking cessation in the treatment of tobacco use. Health Serv Insights. 2013;6:79–85.

19. Stead LF, Carroll AJ, Lancaster T. Group behaviour therapy programmes for smoking cessation. Cochrane Database Syst Rev. 2017 Mar 31;3:CD001007.

20. Andrews JO, Mueller M, Dooley M, Newman SD, Magwood GS, Tingen MS. Effect of a smoking cessation intervention for women in subsidized neighborhoods: A randomized controlled trial. Prev Med. 2016 Sep;90:170–6.

21. Jm S, Al S, Me M, Ka D, Gf M. Bupropion and cognitive-behavioral therapy for smoking cessation in women. Nicotine Tob Res Off J Soc Res Nicotine Tob. 2007 Jun 1;9(6):699–709.

22. Slovinec D'Angelo ME, Reid RD, Hotz S, Irvine J, Segal RJ, Blanchard CM, et al. Is stress management training a useful addition to physician advice and nicotine replacement therapy during smoking cessation in women? Results of a randomized trial. Am J Health Promot AJHP. 2005 Dec;20(2):127–34.

23. Hartmann-Boyce J, Chepkin SC, Ye W, Bullen C, Lancaster T. Nicotine replacement therapy versus control for smoking cessation. Cochrane Database Syst Rev. 2018 May 31;5:CD000146.

24. Agboola S, McNeill A, Coleman T, Bee JL. A systematic review of the effectiveness of smoking relapse prevention interventions for abstinent smokers. Addiction. 2010;105(8):1362–80.

25. Mersha AG, Gould GS, Bovill M, Eftekhari P. Barriers and Facilitators of Adherence to Nicotine Replacement Therapy: A Systematic Review and Analysis Using the Capability, Opportunity, Motivation, and Behaviour (COM-B) Model. Int J Environ Res Public Health [Internet]. 2020 Dec [cited 2021 Mar 24];17(23). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7731205/

26. Fullerton D, Bauld L, Dobbie F. We Can Quit - Findings from the Action Research Study - Full Report [Internet]. Dublin, Ireland: Irish Cancer Society; 2015 [cited 2021 Mar 24]. Available from: https://www.cancer.ie/cancer-information-and-support/cancer-prevention/smoking/we-can-quit/more-information-about-we-can-quit

27. Hayes C, Ciblis A, Darker C, Dougall N, Vance J, O'Connell N, et al. We Can Quit2 (WCQ2): a community-based intervention on smoking cessation for women living in disadvantaged areas of Ireland—study protocol for a pilot cluster randomised controlled trial. Pilot Feasibility Stud. 2019 Nov 23;5(1):138.

28. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. Health Educ Q. 1988;15(4):351–77.

29. Minkler M, Blackwell AG, Thompson M, Tamir H. Community-Based Participatory Research: Implications for Public Health Funding. Am J Public Health. 2003 Aug;93(8):1210–3.

30. Hayes C, Patterson J, Castello S, Burke E, O'Connell N, Darker Catherine D, et al. 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. in submission;

31. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015 Mar 19;350:h1258.

32. Gillies K, Chalmers I, Glasziou P, Elbourne D, Elliott J, Treweek S. Reducing research waste by promoting informed responses to invitations to participate in clinical trials. Trials. 2019 Oct 28;20(1):613.

33. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. BMJ. 2000 Sep 16;321(7262):694–6.

34. A F, M W, R L, J W, R P, R B, et al. Pilot trial and process evaluation of a multilevel smoking prevention intervention in further education settings. Public Health Res [Internet]. 2017 Oct 25 [cited 2021 Mar 24];5(8). Available from: https://www.journalslibrary.nihr.ac.uk/phr/phr05080#/abstract

35. Jones SE, Hamilton S, Bell R, Araujo-Soares V, White M. Acceptability of a cessation intervention for pregnant smokers: a qualitative study guided by Normalization Process Theory | BMC Public Health | Full Text. BMC Public Health [Internet]. 2020 [cited 2021 Mar 24];20(1512). Available from: https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-020-09608-2

36. Peiris D, Wright L, News M, Rogers K, Redfern J, Chow C, et al. A Smartphone App to Assist Smoking Cessation Among Aboriginal Australians: Findings From a Pilot Randomized Controlled Trial. JMIR MHealth UHealth. 2019 Apr 2;7(4):e12745.

37. European Commission. General Data Protection Regulation (GDPR). 2018.

38. Teddlie C, Tashakkori A. Overview of contemporary issues in mixed methods research. In: SAGE Handbook of Mixed Methods in Social and Behavioral Research. 2nd Edition. SAGE Publications, Inc; 2010. p. 1–42.

39. Teddlie C, Tashakkori A. Foundations of mixed methods research: integrating quantitative and qualitative approaches in the social and behavioral sciences. Los Angeles: SAGE; 2009.

40. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs-principles and practices. Health Serv Res. 2013 Dec;48(6 Pt 2):2134–56.

41. Creswell JW, Clark VL, Gutman LM, Hanson. Advanced mixed methods research designs. In: Handbook of mixed methods in social and behavioral research. Thousand Oaks, California: Sage; 2003.

42. Thomas DR. A General Inductive Approach for Analyzing Qualitative Evaluation Data. Am J Eval. 2006 Jun 1;27(2):237–46.

43. Cahill K, Stevens S, Perera R, Lancaster T. Pharmacological interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database Syst Rev [Internet]. 2013 [cited 2022 May 19];(5). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD009329.pub2/full

44. Health Service Executive. What is the role of the PCRS? [Internet]. Dublin, Ireland: HSE - Health Service Executive; 2019 [cited 2021 Apr 21]. Available from: https://www.hse.ie/eng/staff/pcrs/about-pcrs/

45. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. Adm Policy Ment Health. 2015 Sep;42(5):533–44.

46. Health Service Executive. National Standard for Tobacco Cessation Support Programme Ireland [Internet]. 2013. Available from: https://www.hse.ie/eng/about/who/tobaccocontrol/cessation/tobacco-cessation-support-programme.pdf

47. National Adult Literacy Agency. Plain English Service [Internet]. Dublin, Ireland: NALA; 2022 [cited 2022 May 19]. Available from: https://www.nala.ie/plain-english/

48. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care J Int Soc Qual Health Care ISQua. 2007 Dec;19(6):349–57.

49. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77–101.

50. Nowell LS, Norris JM, White DE, Moules NJ. Thematic Analysis: Striving to Meet the Trustworthiness Criteria. Int J Qual Methods. 2017 Dec 1;16(1):1609406917733847.

51. Saunders B, Sim J, Kingstone T, Baker S, Waterfield J, Bartlam B, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. Qual Quant. 2018 Jul 1;52(4):1893–907.

52. Patton MQ. Qualitative Evaluation and Research Methods. SAGE Publications; 1990. 381–384 p.

53. NICE. Stop smoking interventions and services [Internet]. Department of Health, UK; 2018 [cited 2019 Nov 28]. Available from: https://www.nice.org.uk/guidance/ng92/chapter/Recommendations#evidence-based-stop-smoking-interventions

54. Bartlett R, Brown L, Shattell M, Wright T, Lewallen L. Harm Reduction: Compassionate Care Of Persons with Addictions. Medsurg Nurs Off J Acad Med-Surg Nurses. 2013;22(6):349–58.

55. Stubbs B, Veronese N, Vancampfort D, Prina AM, Lin PY, Tseng PT, et al. Perceived stress and smoking across 41 countries: A global perspective across Europe, Africa, Asia and the Americas. Sci Rep. 2017 Aug 8;7(1):7597.

56. Minami H, Yeh VM, Bold KW, Chapman GB, McCarthy DE. Relations among Affect, Abstinence Motivation and Confidence, and Daily Smoking Lapse Risk. Psychol Addict Behav J Soc Psychol Addict Behav. 2014 Jun;28(2):376–88.

57. Bonevski B, Twyman L, Paul C, D'Este C, West R, Siahpush M, et al. Comparing socially disadvantaged smokers who agree and decline to participate in a randomised smoking cessation trial. BMJ Open [Internet]. 2015 Sep 1 [cited 2019 Nov 29];5(9). Available from: https://bmjopen.bmj.com/content/5/9/e008419

58. Murray RP, Johnston JJ, Dolce JJ, Lee WW, O'Hara P. Social support for smoking cessation and abstinence: The lung health study. Addict Behav. 1995 Mar 1;20(2):159–70.

59. Pirie PL, Rooney BL, Pechacek TF, Lando HA, Schmid LA. Incorporating social support into a community-wide smoking-cessation contest. Addict Behav. 1997 Jan 1;22(1):131–7.

60. Walsh CA, Al Achkar M. A qualitative study of online support communities for lung cancer survivors on targeted therapies. Support Care Cancer Off J Multinatl Assoc Support Care Cancer. 2021 Aug;29(8):4493–500.

61. Bryant J, Bonevski B, Paul C, O'Brien J, Oakes W. Developing cessation interventions for the social and community service setting: A qualitative study of barriers to quitting among disadvantaged Australian smokers. BMC Public Health. 2011 Jun 24;11:493.

62. Miller N, Frieden TR, Liu SY, Matte TD, Mostashari F, Deitcher DR, et al. Effectiveness of a large-scale distribution programme of free nicotine patches: a prospective evaluation. Lancet Lond Engl. 2005 Jun 28;365(9474):1849–54.

63. McClure JB, Swan GE. Tailoring Nicotine Replacement Therapy. CNS Drugs. 2006 Apr 1;20(4):281–91.

64. Kotz D, West R. Explaining the social gradient in smoking cessation: it's not in the trying, but in the succeeding. Tob Control. 2009 Feb 1;18(1):43–6.

65. Beard E, McNeill A, Aveyard P, Fidler J, Michie S, West R. Association between use of nicotine replacement therapy for harm reduction and smoking cessation: a prospective study of English smokers. Tob Control. 2013 Mar;22(2):118–22.

66. Hughes JR, Pillitteri JL, Callas PW, Callahan R, Kenny M. Misuse of and dependence on over-the-counter nicotine gum in a volunteer sample. Nicotine Tob Res. 2004 Feb 1;6(1):79–84.

67. Balmford J, Borland R, Hammond D, Cummings KM. Adherence to and Reasons for Premature Discontinuation From Stop-Smoking Medications: Data From the ITC Four-Country Survey. Nicotine Tob Res. 2011 Feb 1;13(2):94–102.

68. Yerger VB, Wertz M, McGruder C, Froelicher ES, Malone RE. Nicotine Replacement Therapy: Perceptions of African-American Smokers Seeking to Quit. J Natl Med Assoc. 2008 Feb 1;100(2):230–6.

69. Zinser MC, Pampel FC, Flores E. Distinct beliefs, attitudes, and experiences of Latino smokers: relevance for cessation interventions. Am J Health Promot AJHP. 2011 Jun;25(5 Suppl):eS1-15.

70. Shiffman S, Hughes JR, Marino MED, Sweeney CT. Patterns of over-the-counter nicotine gum use: persistent use and concurrent smoking. Addiction. 2003;98(12):1747–53.

71. Shiffman S, Hughes JR, Pillitteri JL, Burton SL. Persistent use of nicotine replacement therapy: an analysis of actual purchase patterns in a population based sample. Tob Control. 2003 Sep 1;12(3):310–6.

72. OECD. Survey Results for Ireland from the OECD's Programme for the International Assessment of Adult Competencies [Internet]. Dublin, Ireland: Central Statistics Office; 2013 [cited 2021 Mar 24]. Available from: http://www.oecd.org/skills/piaac/Ireland.pdf

73. Muir KW, Lee PP. Literacy and Informed Consent. Arch Ophthalmol. 2009 May;127(5):698–9.

74. Parikh NS, Parker RM, Nurss JR, Baker DW, Williams MV. Shame and health literacy: the unspoken connection. Patient Educ Couns. 1996 Jan;27(1):33–9.

75. van Veen EB. Observational health research in Europe: understanding the General Data Protection Regulation and underlying debate. Eur J Cancer. 2018 Nov 1;104:70–80.

76. Hennessey ML, Rumrill J. Treatment fidelity in rehabilitation research. J Vocat Rehabil. 2003 Jan 1;19(3):123–6.

77. Slaughter SE, Hill JN, Snelgrove-Clarke E. What is the extent and quality of documentation and reporting of fidelity to implementation strategies: a scoping review. Implement Sci. 2015 Sep 7;10(1):129.

78. Breitenstein SM, Gross D, Garvey CA, Hill C, Fogg L, Resnick B. Implementation fidelity in community-based interventions. Res Nurs Health. 2010 Apr;33(2):164–73.

79. O'Shea O, McCormick R, Bradley JM, O'Neill B. Fidelity review: a scoping review of the methods used to evaluate treatment fidelity in behavioural change interventions. Phys Ther Rev. 2016 Nov 1;21(3–6):207–14.

80. Bellg AJ, Borrelli B, Resnick B, Hecht J, Minicucci DS, Ory M, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. Health Psychol Off J Div Health Psychol Am Psychol Assoc. 2004 Sep;23(5):443–51.

81. Toomey E, Hardeman W, Hankonen N, Byrne M, McSharry J, Matvienko-Sikar K, et al. Focusing on fidelity: narrative review and recommendations for improving intervention fidelity within trials of health behaviour change interventions. Health Psychol Behav Med. 2020 Jan 1;8(1):132–51.

82. World Health Organization. Through a gender lens. Women and tobacco in the WHO European Region [Internet]. Copenhagen: WHO Regional Office for Europe; 2021 [cited 2021 Aug 10]. Available from: https://apps.who.int/iris/bitstream/handle/10665/339328/WHO-EURO-2021-1847-41598-56811-eng.pdf

Figure caption

Figure 1. Coding frame for the qualitative results, categorised into **(a)** 'Programme level' and **(b)** 'Trial level' results following the UK MRC process evaluation framework.

Figure legend

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.

Additional files

Name: Additional file 1

File format: .docx

Title of data: 12-week follow up semi-structured interview guide, WCQ2 women participants

Description of data: Interview guide for WCQ2 participants.

Name: Additional file 2

File format: .docx

Title of data: 12 week follow up semi-structured focus group guide, WCQ2 Community Facilitators

Description of data: Interview guide for Community Facilitators

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