

1 **Title: A process evaluation of ‘We Can Quit’: a community-based smoking**
2 **cessation intervention targeting women from areas of socio-disadvantage in**
3 **Ireland**

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23

24 **Abstract (346/350)**

25 **Background:** Smoking poses a serious risk of early preventable death and disease
26 especially for women living with socio-economic disadvantage (SED). A smoking
27 cessation programme, 'We Can Quit', was developed in Ireland tailored to SED
28 women. This includes group-based support delivered by trained lay local community
29 facilitators (CFs) and free nicotine replacement therapy (NRT). The intervention was
30 pilot tested in a cluster randomised controlled trial, 'We Can Quit 2'. This paper
31 reports on the WCQ2 process evaluation which assessed feasibility and acceptability
32 of the programme and trial processes.

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

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

47 trial team to make materials (e.g., participant intervention booklet; consent forms and
48 participant information leaflets) accessible while also meeting requirements under
49 2018 European General Data Protection Regulation legislation. Hypothetical
50 scenarios of direct (e.g., researcher present during programme delivery) and indirect
51 (e.g., audio recordings of programme sessions) observational fidelity assessments
52 for a future definitive trial (DT) were acceptable.

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

58

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

61

62 **Trial registration:** WCQ2 pilot trial (ISRCTN registration 74721694)

63

64 **Background**

65 Tobacco use is the main cause of preventable death worldwide (1) and has been
66 causally related to a variety of chronic diseases and fourteen types of cancer (2),
67 including lung cancer (3). In Ireland, as in most high-income countries, smoking
68 prevalence and associated health consequences are greater in socioeconomically
69 disadvantaged (SED) populations (4–6). Social determinants that exacerbate health

70 inequalities are associated with psychosocial factors, such as high daily stress, lack
71 of social support, and pro-smoking social norms (7–9).

72

73 Gender is also a determinant of smoking (10). A review of evidence from
74 effectiveness trials have indicated that women are less likely to quit smoking and
75 have greater difficulty maintaining long-term smoking abstinence than men (11). In
76 Ireland, this is reflected in increased lung cancer incidence among women between
77 1994-2015. Lung cancer is now the main cause of mortality from cancer in women
78 in Ireland (12,13).

79

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

86

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

92

93 Group-based behavioural interventions involve the delivery of behavioural
94 techniques, specific advice, and support from other participants (18). Although group
95 support is more effective than self-help, more evidence is needed to determine its
96 effectiveness compared to intensive individual counselling and in sub-groups of
97 smokers (19), such as SED women. To date, the evidence on the effectiveness of
98 group-based smoking cessation interventions tailored to women is scarce (20–22).
99 Only one previous randomised controlled trial (RCT) has evaluated a group-based
100 cessation intervention tailored to the specific needs of disadvantaged African-
101 American women, with positive abstinence rates (20). Findings from other studies
102 have shown that the use of nicotine replacement therapy (NRT) increases the rate of
103 quitting by 50% to 60%, regardless of setting (23), and can help to prevent smoking
104 relapse (24). However, the cost of NRT has hindered access and potential benefits
105 to SED smokers (9,25).

106

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

115

116 Trial evaluations typically focus on understanding whether interventions are effective
117 but cannot explain how and why interventions succeed or fail in attaining outcomes.
118 This is particularly important to definitive trials (DTs) of complex interventions (31).
119 Of growing importance is the need to understand why interventions succeed or fail in
120 the pilot trial phase (such as WCQ2), thereby allowing earlier design adaptations
121 before progression to DT (32). A process evaluation, as outlined by the UK Medical
122 Research Council (MRC)(31), provides a framework for assessing an intervention's
123 implementation, the identification of contextual factors and proposed mechanisms for
124 change. It is considered an essential part of designing and testing complex
125 interventions and complements earlier UK MRC guidance (33). Hence, a qualitative,
126 mixed-method process evaluation was embedded into the WCQ2 trial, following UK
127 MRC specific guidance(31). To our knowledge few smoking cessation feasibility
128 trials have applied UK MRC process evaluation guidance, with only one completing a
129 process similar to the current study (34). Others examined acceptability of the
130 cessation intervention only from the perspectives of participants, overlooking the
131 assessment of trial processes acceptability(35,36).

132

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

139

140 **Methods**

141 ***Design***

142 This research is embedded within a larger trial which took the philosophical stance of
143 ‘pragmatism’, which is the most commonly stated philosophy supporting mixed
144 methods research (38–41). Pragmatism values both objective and subjective
145 knowledge, and investigators using both quantitative and qualitative data, adopt a
146 postmodern viewpoint and employ a reflective lens of the social, environmental, and
147 other contexts at play. In this tradition, knowledge is constructed using data through
148 the adoption of an inductive-deductive logic, thereby increasing the credibility of the
149 research findings (39). This aspect of the trial embraces a qualitative research
150 design, using face-to-face individual and paired interviews. An inductive approach,
151 where the research team attempted to make sense of context and data without
152 imposing pre-existing expectations on the topic under inquiry, was used (42).
153 Stakeholder interviews are a common method of inquiry as outlined by the UK
154 MRC’s framework to ‘capture emerging changes in implementation, experiences of
155 the intervention and unanticipated or complex causal pathways’ (31). The School of
156 Medicine Research Ethics Committee, Trinity College Dublin, approved this study
157 (Reference number 20170404). All research procedures have been performed in
158 accordance with the Declaration of Helsinki.

159

160 ***WCQ2 pilot trial overview***

161 Participants were recruited in four consecutive waves, each one in a matched SED
162 district (27). Treatments were the WCQ intervention, which comprised 12 weeks of
163 group-based behavioural support and optional access to combination NRT (43)

164 without charge for all women (e.g., patches, with either inhalator, gum, lozenges or
165 spray). The WCQ intervention also included advice from community pharmacists to
166 support NRT use (e.g., titration of NRT amounts). In Ireland, patients entitled to the
167 General Medical Scheme (GMS) are eligible for low or no cost prescriptions(44),
168 while non-GMS 'private' patients typically pay directly for NRT. CF activities focused
169 on increasing self-efficacy; on peer-support by sharing experiences at sessions and
170 celebrating achievements with family, friends, and the local community (26,27).
171 WCQ participants also received an intervention booklet which included fact sheets,
172 activity worksheets, a handheld NRT record, and signposting information. They were
173 invited to keep a smoking journal to use as a personal space for reflections from the
174 first session to increase their understanding of their smoking behaviour.

175

176 ***Selection of participants***

177 A purposive sampling procedure was employed, targeting key stakeholders involved
178 in the trial. The focus of recruitment was to identify and select information-rich cases
179 (45) from whom it was possible to learn about experiences of programme recipients,
180 the facilitators who delivered the intervention and to elucidate participants'
181 experiences of being involved in a pilot RCT. Key participant characteristics and
182 outcome assessment at follow up, including self-reported smoking behaviours at
183 baseline are shown in Table 1.

184

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

Socio-demographics	
Age mean, (SD)	52.1, (10.7)
Marital Status	<i>n</i> (%)
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

194 ***Description of Community Facilitators (CFs)***

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

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

206

207 ***Procedure***

208 At the end of the programme, all participants who attended at least one group
209 session were contacted by telephone and invited for interview. A semi-structured
210 interview schedule allowed for probing, follow-up questions and flexibility. Interview
211 schedules were piloted. (See Additional Files 1 and 2 for sample interview schedules
212 for participants and CFs). Interviews were face-to-face and occurred between June
213 2018 and May 2019 at times and locations convenient to participants. Only the
214 interviewer (EB; female; MSc-level training; full-time trial research assistant) and
215 interviewees were present. The interviewer was known to interviewees at the time of
216 interviews from previous contact regarding recruitment and follow up within the trial.
217 Each interview lasted on average 20-30 minutes, while CF interviews lasted

218 approximately an hour. Participant interviews were conducted individually, while
219 interviews with CFs (two CFs per intervention site) were conducted together.
220 Interviews were audio recorded and transcribed verbatim by a professional
221 transcriber. Observational field notes were completed to enhance data and provide
222 context for analysis. A participant information leaflet (PIL) was provided to
223 participants. Informed written consent was obtained prior to commencing interviews
224 and participation was voluntary. Efforts were made to explain complex terminology in
225 layperson's language in the consent form and the PIL by also engaging with the
226 National Adult Literacy Agency (NALA)(47). A necessary balance was needed in
227 order to include sufficient detail to comply with legislation such as GDPR(37). The
228 Research Assistant (EB) verbally explained all trial processes to participants to
229 maximise informed consent. The PIL and consent forms were given to each
230 participant at least 24 hours before signing, affording participants time to review.

231

232 To ensure anonymity, participants were given identification tags (e.g., W1-CF1,
233 which corresponds to Wave 1 of recruitment, Community Facilitator 1; W3-P0004,
234 which corresponds to Wave 3 of recruitment, participant number 0004). Reporting of
235 the study methods have followed published standards for undertaking and reporting
236 qualitative research (COREQ) (48).

237

238 ***Data analysis***

239 Thematic analysis, a recognised method to identify, analyse, organise, describe, and
240 report themes found within qualitative data, was used (49). Data were coded in six
241 phases: familiarisation with data, generating initial codes, searching for themes

242 among codes, reviewing themes, defining and naming themes through the
243 production of a 'coding frame', and producing the final analyses through the
244 application of the coding frame to available data (49). The use of a coding frame
245 allows for the organisation of codes, to encourage trustworthiness of the data
246 through each phase of thematic analyses (50). NVivo version 12 software was used
247 to organise data into themes and nodes.

248

249 Three researchers (CD, KOS & EB) independently read all transcripts. Rigorous line-
250 by-line coding was applied, with a focus on experiential claims and concerns. Data
251 patterns were clustered into a thematic structure to identify and categorise major
252 themes and sub-themes. Data saturation was achieved when no new codes or
253 themes emerged within the analyses (51). Any differences in interpretation were
254 resolved through discussion. A fourth independent researcher (JI) with qualitative
255 expertise, reviewed the coding frame and applied it to approximately 10% of
256 transcripts, improving analytical triangulation (52). Transcripts were not returned to
257 participants.

258

259 **Results**

260 Of 50 women invited, 21 were interviewed (this corresponded to a total of 3, 7, 5 and
261 6 women from Waves 1 to 4 respectively; 41% response rate) within the timeframe
262 (one to two weeks post final programme session). The full cohort of CFs were
263 interviewed, two in each of the four intervention sites, resulting in a total of eight CFs
264 interviews.

265

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

269

270 ***Category I. Programme level results***

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

272

273 **Theme 1. Nicotine Replacement Therapy (NRT)**

274 *Subtheme 1.1. Cost of and access to NRT*

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

277

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

280

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

286

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

289

290 W4–CF 1: *And then when the pharmacists confronted the ladies about the*
291 *prescription they kind of were uncomfortable that they felt em they were*
292 *being put under a bit of pressure to get the prescription off their doctor and*
293 *they were stressing over it.*

294

295 *Subtheme 1.2. Views, beliefs, and opinions about NRT*

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

298

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

302

303 Other concerns related to its perceived potential for dependence.

304

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

308

309 *Subtheme 1.3. Role of the community pharmacist*

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

314

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

319

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

326

327 W2–CF 1: *....they had their moments and they'd arrive in the door to*
328 *him...And he'd [pharmacist] a little room to the side and he'd take them in*
329 *and talk it through with them. The chat with the pharmacist really kept them*
330 *going in their quit attempts. They'd arrive down to him sometimes in a panic.*

331

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

335

336 W4–CF 2: *No, the pharmacist didn't come in because they couldn't, they didn't*
337 *want to stand up and talk in front of people.*

338

339 **Theme 2. Group Support and Community Facilitators**

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

342 Participants were very accepting of role-modelling behaviours which
343 demonstrated that stopping smoking was possible which featured as part of the
344 group sessions.

345

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

349

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

353

354 *W2–P0041: Well, I found when I came first that everybody was the same as*
355 *me...You only just felt we're all here together on the same wavelength....*
356 *Normally when I give up the cigarettes, I feel that somebody has after gone*
357 *from my life, I'm after losing a friend, I'd be pining but this time I says, 'no I'm*
358 *not losing a friend'. So, something worked in the head.*

359

360 Participants' spoke of embracing and accepting group support in terms of building
361 capacity by increasing their skills, self-efficacy, and support for maintaining
362 abstinence. The group support they received strengthened and reinforced their
363 intentions to cease or decrease smoking.

364

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

366 *dissemination*

367 In practice, participants often provided informational support to one another, offering
368 advice and suggestions about smoking cessation strategies through an informal
369 exchange process.

370

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

375

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

378

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

381

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

384

385 *W3-CF 1: ...it became a nice comfortable space to be in and I think that's*
386 *what encouraged them to come back. Yes, and for the weeks where they*
387 *were feeling a bit vulnerable and a bit low and a bit judge[d] and self-*
388 *berating, the other women in the group expressed their encouragement and*
389 *compassion.*

390

391

392 *Subtheme 2.3. Importance of non-judgemental interactions*

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

396

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

401

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

404

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

409

410 *Subtheme 2.4. Trust and confidentiality*

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

413

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

416

417 Women reported freedom to discuss their general life stresses and the stress
418 experienced *vis-a-vis* making a quit attempt.

419

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

425

426

427 **Category II. Trial level results**

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

430

431 **Theme 3. Feasibility and acceptability of data collection methods and measures**

432 *Subtheme 3.1. Provision of a salivary sample.*

433 Biochemical verification of smoking status is standard in smoking cessation trials to
434 evaluate intervention effectiveness. We asked participants about their experience of
435 providing a salivary sample. Some participants found the process acceptable.

436

437 W1–P0040: *That was grand, but it got stuck in your mouth trying to get it wet.*
438 *Me mouth was lovely and wet before it went in and then all of a sudden it just*

439 *dried up and I wasn't sure whether it was wet enough or not. No, it wasn't a*
440 *problem because it has to be studied.*

441

442 However, others reported that the process of providing the salivary sample was not
443 feasible for them.

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

446

447 *Subtheme 3.2. Literacy levels.*

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

451

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

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

461

462 The CFs were very experienced in delivering community education programmes in
463 SED communities so they were familiar and sensitive to low literacy. One CF had a
464 background as a literacy tutor in a different role and she shared her insights:

465 *W3–CF 2: You can see that straight off when you go into a room because*
466 *there's the tell-tale signs, people are forgetting their glasses and forgetting*
467 *their journals the second week.... they don't realise about the journal and*
468 *that can be very off-putting when a person... They can see that it's like a*
469 *workbook as well and that there's writing to be done. And often... we always*
470 *stress that this journal is yours and it's not for us to see and what you do in it*
471 *is your business...*

472

473 *Subtheme 3.3. Use of repeated measures.*

474 As a part of the trial processes, questionnaire data were collected at baseline, and at
475 12-weeks and six-months post-intervention. Women reported satisfactory
476 understanding of the necessity for multiple data collection timepoints.

477

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

481

482 There was mixed acceptability relating to the process of providing a biological
483 sample on more than one occasion, although they agreed to it, with one woman
484 stating:

485

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

489

490 **Theme 4. Fidelity**

491 *Subtheme 4.1. Tailoring sessions to trial checklist instead of intervention*

492 *manual*

493 Fidelity to the intervention manual was assessed by self-report methods through a
494 checklist of intervention sessional components, completed after each session by the
495 CFs (27). Generally, CFs were accepting of this process and gave a positive reaction
496 to the fidelity checklist:

497

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

501

502 However, there was a sense from the CFs that their use of the fidelity checklist went
503 further than just a behavioural prompt for sessional content delivery and was
504 discussed in terms of conscious efforts to change delivery of sessions.

505

506 W2–CF 2: *You kind of are watching a lot more.....because we had to chart*
507 *everything and you were more inclined to try and stay on course... this time*
508 *around, I made much more of an effort to stick to the plan.*

509

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

512

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

516

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

518 Hypothetical scenarios were presented regarding alternative fidelity assessment
519 methods. These included direct observational methods (e.g., having a researcher
520 present in the room during group sessions) or indirect methods (e.g., audio recording
521 of sessions and assessed at a later stage by the research team). There were some
522 concerns relating to the acceptability of these proposed processes as a perceived
523 threat to session privacy, and whether an audio recording could interfere with the
524 dynamic of the session:

525

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

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

531

532 However, there were no concerns about having an independent observer changing
533 the group dynamic from other CFs.

534

535 W3–CF 2: *I certainly wouldn't have an issue; I can understand what the*
536 *research is for... I don't think that would have stopped anybody [from*
537 *speaking].*

538

539

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

542

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

545

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

549

550 W2–P0001: *So long as it was falling into the right hands and it was for*
551 *research and was going to help people and maybe make the course better to*
552 *help other people give up the cigarettes then [I've] no problem with it.*

553

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

556

557 **Discussion**

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

570

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

583 There are different types of social support. Firstly, structural support is the presence
584 of family/ friends/social networks within a person's life. Secondly, functional support
585 is the quality of those relationships. This includes emotional support (empathetic
586 listening), and instrumental support (e.g., practical assistance/information provision).
587 A third type of "support" (or its opposite) is the smoking behaviour of close others in
588 the persons environment (e.g., partners, friends, and colleague's). These three
589 aspects of social support are closely interrelated and were reported as present and
590 acceptable in WCQ2. These are also important factors as mechanisms for change
591 within the theory of SEM (28) which underpins the programme.

592

593 Several community-based health behaviour change interventions have included the
594 support of a 'buddy' from within participants' existing social network, and found this
595 to be correlated with smoking cessation (58,59). Although WCQ2 did not formally
596 ask participants to select a 'buddy', participants reflected that some of their
597 motivation was a desire not let down other members of the group. This type of
598 camaraderie is typically seen in groups that have known each other a long time (60),
599 however, it was reported as present in WCQ2 during a short 12-week period.

600

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

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

619

620 Participants' expressed concerns about the potential side effects of NRT, which are
621 in line with previous findings (65), and may act as a barrier towards its use in the
622 long-term, or incorrect or under-use (66,67). Concerns about becoming 'addicted' to
623 NRT and about the health consequences associated with NRT are commonly held
624 beliefs by many smokers and ex-smokers (68,69). This is despite the low risk of NRT
625 addiction (70,71) which is heavily outweighed by smoking risks. In three of the four
626 waves women spoke highly of pharmacists and would often present to them between
627 intervention sessions for additional support. Payment in this pilot trial for
628 pharmacists' time related to the dispensing of NRT with their professional guidance
629 around medication usage only. Future DT research should comprehensively map
630 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

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

668

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

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

688

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

696

697 The study had a number of strengths including the application of the UK MRC
698 process evaluation guidance (31) within a community based smoking cessation trial.
699 Recently, the WHO has recognised the urgency of addressing tobacco use in
700 women and the need for tailored interventions targeting specific groups of women
701 (82). This study focused on gaining the views of a population that is considered ‘hard
702 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

727 **Conclusions**

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

737

738 **List of abbreviations**

739 SED: socioeconomically disadvantaged population

740 WHO: World Health Organization

741 RCT: randomised controlled trial

742 NRT: nicotine replacement therapy

743 WCQ2: We Can Quit2

744 WCQ: We Can Quit

745 CFs: community facilitators

746 DT: definitive trial

747 UK MRC: UK Medical Research Council

748 HSE: Health Service Executive

749 GMS: General Medical Scheme

750 GP: general practitioner

751

752 **Declarations**

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

758 ***Consent for publication.*** Not applicable.

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

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

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768 ***Authors' contributions.*** CBH as PI, and CD, JV, LB and ND as co-PIs, acquired
769 funding for the WCQ2 trial. CBH directed all study components. CD led the design
770 and analysis of the process evaluation with significant input from FD, PW, JV, KL,
771 CBH in conceptualisation, and EB, and KOS in data analysis and validation. EB

772 carried out the interviews. NO'C, CR and AB, coordinated the implementation. The
773 manuscript was drafted by CD, SC and CBH. Tables and figures were prepared by
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787

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1016

1017 **Figure caption**

1018 **Figure 1.** Coding frame for the qualitative results, categorised into **(a)** ‘Programme
1019 level’ and **(b)** ‘Trial level’ results following the UK MRC process evaluation
1020 framework.

1021

1022 **Figure legend**

1023 **Medical Research Council Process Evaluation Framework:**

1024 **1 Context** (e.g., contextual factors that shape theories of how the intervention works;
1025 contextual factors that affect (and may be affected by) implementation, intervention
1026 mechanism and outcomes; causal mechanism present within the context which act
1027 to sustain the status quo or potentiate effects)).

1028 **2 Implementation** (e.g., implementation process (how delivery is achieved; training,
1029 resources, etc); what is delivered – fidelity, dose, adaptations, reach).

1030 **3 Mechanism of impact** (e.g., participant responses to and interactions with the
1031 intervention; mediators; unexpected pathways and consequences.

1032

1033 **Additional files**

1034 Name: Additional file 1

1035 File format: .docx

1036 Title of data: 12-week follow up semi-structured interview guide, WCQ2 women
1037 participants

1038 Description of data: Interview guide for WCQ2 participants.

1039

1040 Name: Additional file 2

1041 File format: .docx

1042 Title of data: 12 week follow up semi-structured focus group guide, WCQ2
1043 Community Facilitators

1044 Description of data: Interview guide for Community Facilitators

1045

1046

1047

1048