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An application of PRECIS-2 to evaluate trial design in a pilot cluster randomised controlled trial of a community-based smoking cessation intervention for women living in disadvantaged areas of Ireland

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Pilot and Feasibility Studies

An application of PRECIS-2 to evaluate trial design in a pilot cluster randomised controlled trial of a community-based smoking cessation intervention for women living in disadvantaged areas of Ireland

--Manuscript Draft--

Manuscript Number:	PAFS-D-21-00231	
Full Title:	An application of PRECIS-2 to evaluate trial design in a pilot cluster randomised controlled trial of a community-based smoking cessation intervention for women living in disadvantaged areas of Ireland	
Article Type:	Research	
Funding Information:	health research board (DIFA-2017-048)	Dr Catherine B Hayes
Abstract:	<p>Background "We Can Quit2" (WCQ2) was a pilot cluster randomised controlled trial with an embedded process evaluation assessing the feasibility and acceptability of 'We Can Quit' (WCQ), a peer-delivered community-based stop-smoking programme for women in disadvantaged communities. The control group comprised 'enhanced usual care' offered by the Irish Health Service Executive (HSE). The PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2) is a tool to assess whether a trial design is more explanatory (working under ideal conditions) or pragmatic (working under 'real world' conditions). The aim of this paper was to retrospectively evaluate the WCQ2 pilot trial using PRECIS-2 to inform the decision-making process on progression to a future definitive trial (DT).</p> <p>Methods The WCQ2 trial protocol and HSE standard stop-smoking service were described across the nine PRECIS-2 domains: Eligibility, Recruitment, Setting, Organisation, Flexibility-Delivery, Flexibility-Adherence, Follow-up, Primary Outcome. Team members scored the domains as pragmatic or explanatory for each arm in a half-day workshop.</p> <p>Results Seven team members (practitioners and researchers) assessed the overall trial design as more explanatory than pragmatic. Important differences emerged between the two arms. WCQ targeted adult women from disadvantaged communities whereas HSE run a limited enhanced service for all quitters. Recruitment to trial was challenging, intense efforts were needed as the trial proceeded. WCQ was delivered in a non-clinical community setting, HSE services in a clinical setting. WCQ organisation was co-designed with community partners and comprises peer-to-peer group support delivered by trained lay community facilitators, whereas HSE one-to-one support is delivered by Smoking Cessation Officers with a clinical background. Only WCQ allowed flexibility in delivery and adherence. Follow-up was more intensive in WCQ. Greater efforts to improve participant retention will be required in a future DT.</p> <p>Conclusions PRECIS-2 allowed the reflection of practitioners and researchers on similarities and differences between intervention and control arms. Results will inform the decision on progression to an effectiveness DT, which will require more a pragmatic and less explanatory design. This novel use of PRECIS-2 to retrospectively evaluate a complex community-based pilot trial in advance of a full DT will also support learning for those undertaking hybrid trials of implementation and effectiveness.</p>	
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<p>Is this study a clinical trial?</p> <p>A clinical trial is defined by the World Health Organisation as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.</p>	No

Gillian Lancaster
Editor in Chief
Pilot and Feasibility Studies
20/07/2021

Dear Professor Lancaster,

Please consider this manuscript entitled “*An application of PRECIS-2 to evaluate trial design in a pilot cluster randomised controlled trial of a community-based smoking cessation intervention for women living in disadvantaged areas of Ireland*” for publication as a *Pilot and Feasibility Studies* research article.

We Can Quit Too (WCQ2) is a pilot randomised controlled trial to evaluate the feasibility and acceptability of We Can Quit, a group behavioural intervention tailored to women smokers living in socioeconomically disadvantaged districts in Ireland and delivered by trained local lay women in a community setting. A detailed RCT protocol was published in *Pilot Feasibility Stud* (Hayes, et al, 2019, <https://doi.org/10.1186/s40814-019-0511-9>), and the primary results are currently under review.

Our manuscript presents results of the application of the PRagmatic Explanatory Continuum Indicator Summary (PRECIS-2) tool to assess the WCQ2 pilot trial design across the explanatory-to-pragmatic continuum, as a part of the trial process evaluation. To our knowledge, this the first time that PRECIS-2 has been retrospectively used in a complex community-based pilot trial process evaluation to inform the decision on progression to a definitive effectiveness trial.

Our results indicated that the WCQ2 pilot trial design contained more explanatory than pragmatic characteristics. Our findings may also be useful beyond the scope of our study, as they may assist trial teams in designing future pragmatic trials of complex health promotion interventions in community settings. Hence our results and learning points from applying PRECIS-2 to our pilot trial will be of interest to the general *Pilot and Feasibility Studies* readership.

The manuscript has been approved by all the authors, has not been published previously and is not currently under consideration by another journal. The authors have no conflict of interest.

Sincerely,



Catherine Hayes, MD, MPH, FFPHMI, FRCPI, FTCD.
School of Medicine, Trinity College Dublin,
Principal Investigator.

[Click here to view linked References](#)

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6 4 Title: An application of PRECIS-2 to evaluate trial design in a pilot cluster randomised

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8 5 controlled trial of a community-based smoking cessation intervention for women living in

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10 6 disadvantaged areas of Ireland.

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47 24 ^aThese two authors have contributed equally to this work.

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27 **Abstract**

28 Background

29 “We Can Quit2” (WCQ2) was a pilot cluster randomised controlled trial with an embedded
30 process evaluation assessing the feasibility and acceptability of ‘We Can Quit’ (WCQ), a
31 peer-delivered community-based stop-smoking programme for women in disadvantaged
32 communities. The control group comprised ‘enhanced usual care’ offered by the Irish Health
33 Service Executive (HSE). The PRagmatic Explanatory Continuum Indicator Summary
34 (PRECIS-2) is a tool to assess whether a trial design is more explanatory (working under
35 ideal conditions) or pragmatic (working under ‘real world’ conditions). The aim of this paper
36 was to retrospectively evaluate the WCQ2 pilot trial using PRECIS-2 to inform the decision-
37 making process on progression to a future definitive trial (DT).

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38 Methods

39 The WCQ2 trial protocol and HSE standard stop-smoking service were described across the
40 nine PRECIS-2 domains: Eligibility, Recruitment, Setting, Organisation, Flexibility-Delivery,
41 Flexibility-Adherence, Follow-up, Primary Outcome. Team members scored the domains as
42 pragmatic or explanatory for each arm in a half-day workshop.

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65 Results

44 Seven team members (practitioners and researchers) assessed the overall trial design as more
45 explanatory than pragmatic. Important differences emerged between the two arms. WCQ
46 targeted adult women from disadvantaged communities whereas HSE run a limited enhanced
47 service for all quitters. Recruitment to trial was challenging, intense efforts were needed as
48 the trial proceeded. WCQ was delivered in a non-clinical community setting, HSE services in
49 a clinical setting. WCQ organisation was co-designed with community partners and
50 comprises peer-to-peer group support delivered by trained lay community facilitators,
51 whereas HSE one-to-one support is delivered by Smoking Cessation Officers with a clinical

52 background. Only WCQ allowed flexibility in delivery and adherence. Follow-up was more
53 intensive in WCQ. Greater efforts to improve participant retention will be required in a future
54 DT.

55 Conclusions

56 PRECIS-2 allowed the reflection of practitioners and researchers on similarities and
57 differences between intervention and control arms. Results will inform the decision on
58 progression to an effectiveness DT, which will require more a pragmatic and less explanatory
59 design. This novel use of PRECIS-2 to retrospectively evaluate a complex community-based
60 pilot trial in advance of a full DT will also support learning for those undertaking hybrid trials
61 of implementation and effectiveness.

62
63 **Trial registration:** This trial is registered with the ISRCTN registry (No. 74721694),
64 available at <https://doi.org/10.1186/ISRCTN74721694>

65
66 **Key words:** PRECIS-2, pragmatic trial, process evaluation, implementation, smoking
67 cessation, women, deprivation, pilot and feasibility study, trial design.

68 69 **Key messages regarding feasibility**

70 1) What uncertainties existed regarding the feasibility?

- 71 • The PRECIS-2 tool is usually used prospectively in planning trial designs.
72 Retrospective application to a pilot trial as a part of a process evaluation is a novel
73 application.

74 2) What are the key feasibility findings?

- 75 • The application of the PRECIS-2 tool by a multidisciplinary team of researchers and
76 practitioners to retrospectively evaluate the We Can Quit2 pilot trial in terms of

77 pragmatic and explanatory characteristics showed that the trial design was more
78 explanatory than pragmatic.

79 3) What are the implications of the feasibility findings for the design of the main study?

- 80 • Results will inform the decision on progression to a full definitive trial, which will
81 require a more a pragmatic and less explanatory design. They will also support
82 learning for those undertaking future hybrid trials of implementation and
83 effectiveness.

85 **Background**

86 Worldwide, tobacco use causes more than seven million deaths per year, and if this pattern
87 remains unchanged, more than 8 million people a year will die from diseases related to
88 tobacco use by 2030 (1). In Ireland, almost 6,000 smokers die each year from smoking-
89 related diseases (2). Despite a decline in the prevalence of smoking from 23% in 2015 to 17%
90 in 2019, 14% of Irish adults identify themselves as daily smokers (3). There is substantial
91 evidence that people living in poverty carry the heaviest burden of tobacco related premature
92 death and disability (4). This is also true in Ireland, where higher rates of smoking are more
93 likely to occur in more deprived areas (24%), compared to more affluent areas (14%) (3).
94 Research has also demonstrated gender-specific effects in smoking cessation. Women are less
95 likely to achieve smoking abstinence than men (5). There are also differences in terms of
96 smoking cessation treatment needs. Taking Nicotine Replacement Therapy (NRT) in
97 conjunction with high-intensity nonpharmacological support is more effective for women
98 than men (6). NRT and low support were effective for women only at short-term follow-up,
99 whereas men benefited from NRT at all the follow-ups regardless of the intensity of the
100 adjunct support. The results suggested that long-term maintenance of NRT treatment gains
101 decrease more rapidly for women than men (6). A recent review of gender based differences

102 in smoking cessation contended that women have more difficulty in achieving longer term
103 abstinence from smoking than men (5). As reflected internationally, 46% of smokers in
104 Ireland reported a quit attempt in the past 12 months, and 28% have been either trying to quit
105 or planning to do so (3). Capitalizing on this ‘readiness to quit’ is a core feature of many
106 smoking cessation programmes.

107
108 ‘We Can Quit’ (WCQ) is a peer-delivered community-based smoking cessation programme
109 for women smokers from socioeconomically disadvantaged (SED) areas. It was developed by
110 the Irish Cancer Society (ICS), Ireland’s largest cancer charity, in partnership with the
111 National Women’s Council of Ireland, the Institute of Public Health in Ireland and the Health
112 Service Executive (HSE) (7). Key elements are based on the ‘Sister to Sister’ programme in
113 the USA (8, 9). WCQ comprises peer-support group sessions delivered in a community
114 setting, including a combination of behavioural change techniques to enhance readiness to
115 quit, improve self-efficacy and relapse prevention, and access to combination NRT, delivered
116 over a 12-week period. Following a small single-arm feasibility study (7), WCQ was tested in
117 a pilot randomised controlled trial (RCT), ‘We Can Quit 2’ (WCQ2) (10). A process
118 evaluation was embedded in the pilot trial to test the robustness of trial design with respect to
119 delivery of the intervention, implementation processes and key mechanisms of impact, from
120 which to facilitate progression to a full definitive trial.

121
122 Explanatory Randomised Controlled Trials (RCTs) are undertaken in optimal conditions to
123 determine efficacy of interventions, however, the applicability of their results may be limited
124 (11). Pragmatic RCTs maximise the future applicability of results to usual care settings by
125 informing real world decisions of policymakers, clinicians and patients (12). There is a
126 continuum rather than a dichotomy between explanatory and pragmatic trials. PRECIS-2

127 (Pragmatic Explanatory Continuum Indicator Summary) is a tool to assist those involved in
128 multi-disciplinary trial design: trialists, health professionals, and patient representatives, to
129 assess where in this continuum the trial design is placed to ensure it aligns with the desired
130 purpose (12, 13). PRECIS-2 highlights when a trial design does not match “real world”
131 conditions. To date the PRECIS-2 tool has been mainly used to assist in design of a wide
132 range of international definitive trials in service settings, including palliative care services
133 (14) and health promotion interventions (15-17).

134
135 The WCQ2 pilot study was intended to be a pragmatic rather than an explanatory trial (10), in
136 that the design choices aimed to be as close as possible to the ‘real-world’ conditions of
137 smoking cessation services usually delivered in Ireland. In our study, a retrospective
138 evaluation of the WCQ2 pilot trial using PRECIS-2 was conducted to inform the decision-
139 making process on progression to a future definitive trial (DT). The key components of the
140 WCQ intervention and control treatment in real-world community health settings were
141 described through the nine PRECIS-2 domains to assist in evaluation of the trial design along
142 the pragmatic versus explanatory continuum. The WCQ2 trial team members were guided to
143 carefully consider the domains of PRECIS-2 for assessment of applicability of trial design
144 (10). The components of the process evaluation were guided by these domains. While the
145 vast majority of trials use PRECIS-2 as a planning tool for full definitive trials (18), the few
146 that have used the tool at the pilot and feasibility stage have not integrated the tool framework
147 into a process evaluation (19). To our knowledge, WCQ2 is the first study which aimed to
148 retrospectively apply PRECIS-2 in a pilot cluster RCT as a part of the trial process
149 evaluation.

150

151

152 **Methods**

153 *WCQ2 trial overview*

154 WCQ2 was designed as a pilot feasibility cluster RCT seeking to test the feasibility and
155 acceptability of the WCQ programme and trial related features (e.g., randomisation,
156 recruitment, data collection methods), data quality and completion rates at 12 weeks and at
157 six months, and to estimate sample size and appropriateness of design for a future DT. The
158 WCQ2 protocol has been previously published (10). Briefly, the pilot trial was conducted in
159 four consecutive waves in partnership with the HSE and the ICS. Each wave iteratively
160 improved the recruitment strategy protocol, with the final wave successfully achieving the
161 expected recruitment rate.

162 The intervention arm comprised the WCQ programme and the control arm, the HSE's
163 'enhanced usual care' smoking cessation service, a one-to-one service delivered by a
164 specialist smoking cessation professional. The first session was delivered face-to-face, with
165 an option for telephone-based follow-up calls, over six to seven sessions.

166 Results from the trial (manuscript under review) indicated the feasibility and overall
167 acceptability of conducting WCQ in a community setting and constituted valuable data to
168 enhance the design of a future DT to assess the effectiveness of a community-based smoking
169 cessation intervention for women living in SED areas.

170

171 *Description of PRECIS-2*

172 The first three domains 'Eligibility', 'Recruitment' and 'Setting' describe who is included in
173 the trial and where it is carried out. The next three domains, 'Organisation', 'Flexibility in
174 Delivery', and 'Flexibility in Adherence' describe the intervention, what expertise and
175 resources were put into delivering it and what steps are taken to ensure the participants in the
176 trial and the people delivering the intervention adhere to the protocol. The final three

177 domains, 'Follow Up', 'Primary Outcome', and 'Primary Analysis' describe the data from
178 the trial, what and when it collected and how is it analysed.

179 PRECIS-2 has been found to have good interrater reliability and moderate discriminant
180 validity (18).

181
182 To apply PRECIS-2, a detailed description of each domain is collated and each domain is
183 scored from 1-5 using a 5-point Likert scale where 1 indicates a very explanatory design,
184 testing an intervention under ideal conditions and 5 a very pragmatic design, replicating usual
185 care conditions for that domain. Once scores have been allocated to the nine domains, a
186 PRECIS-2 wheel may be plotted for the trial, highlighting design aspects of the trial that are
187 closer to usual care and those which are not. Researchers may then consider whether or not
188 the design matches the purpose of the trial; in the case of an explanatory trial, more tightly
189 controlled trials under ideal conditions that aim to provide understanding of how treatments
190 work; in the case of a pragmatic trial, producing relevant results that can influence clinical
191 practice and be applied to improve healthcare. The Health Research Board in Ireland, which
192 funded the WCQ2 trial, encourages trialists to use PRECIS-2 in their guidance documents
193 (20).

194

195 ***Procedure***

196 A half-day workshop was convened for the WCQ2 trial team (seven individuals) to facilitate
197 use of the PRECIS-2 tool to assess the pragmatism of the pilot feasibility study design. The
198 trial team decided to conduct the workshop in September 2019, when trial data collection was
199 complete, after final wave of the trial, to inform decisions on whether and how to proceed to
200 a definitive RCT. Participants included: one HSE member of staff, two Non-Governmental

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201 Organisation partners including the ICS and four WCQ2 staff (Primary Investigator (PI),
202 trialist focussing on Process Evaluation, research fellow and research assistant).

203

204 *Pre-meeting training*

205 The WCQ2 trial team provided descriptive information on WCQ (intervention arm) and
206 enhanced usual care (control arm) mapped to the nine domains of PRECIS-2 (see Additional
207 file 1), in the weeks prior to the workshop. Information on the WCQ and the HSE standard
208 smoking cessation programmes under real-world conditions was also reviewed against the
209 PRECIS-2 domains and shared with the team beforehand as a part of a description document
210 (Additional file 1). A draft version of this document was circulated among workshop
211 participants for inputs and comments in advance of the meeting.

212

213 The WCQ2 team were given registration details to access the PRECIS-2 website
214 www.PRECIS-2.org to use software to create their own PRECIS-2 study wheel. Individuals
215 were also sent copies of the BMJ elaboration paper for PRECIS-2 (13), and an information
216 sheet to assist in using the PRECIS-2 wheel to score WCQ2. Participants were encouraged to
217 ask questions on using the tool.

218

219 *Half-day workshop*

220 At the meeting, handouts with the WCQ2 PRECIS-2 wheel including domain scores and
221 scoring rationale for each participant were used to facilitate discussion. The draft description
222 document included details of the WCQ intervention and the standard HSE smoking cessation
223 services, and a description of the trial protocol (10) for each of the PRECIS-2 domains.

224

225 The half-day workshop was facilitated by the original PRECIS-2 lead author (KL) to assist in
 226 scoring the domains of the tool. Each participant attending the workshop scored each domain
 227 independently and then a facilitated discussion ensued which allowed individuals to describe
 228 the rationale for their score. Members of the workshop were given an opportunity to change
 229 their score after each individual had given their viewpoint.

230

231 **Results**

232 The results of the PRECIS-2 domain assessments indicating how WCQ2’s original
 233 implementation strategy maps onto the pragmatic-explanatory continuum are detailed in
 234 *Additional File 1*. The facilitated discussion clarified the content describing the WCQ
 235 intervention and enhanced usual care arms. Most of the work for this had been undertaken
 236 earlier through the embedded process evaluation and open sharing of information by the trial
 237 team.

238

239 **Table 1. Composite score PRECIS-2 domains for seven WCQ2 team members*.**

PRECIS-2 domains	Trial PI	Trialist – Process evaluation	Research Fellow	Research Assistant	NGO Partner	NGO Partner	HSE staff
<i>Eligibility</i>	3	4	3	3	3	3	3
<i>Recruitment</i>	2	2	4	2	1	1	1
<i>Setting</i>	4	4	4	4	3	4	4
<i>Organisation</i>	1	1	1	2	2	2	2
<i>Flex delivery</i>	3	3	3	3	3	3	3
<i>Flex adherence</i>	2	2	2	2	3	2	2
<i>Follow up</i>	2	1	2	2	1	1	2
<i>Iry Outcome</i>	1	1	1	1	1	1	1
<i>Iry Analysis</i>	N/A						

*Lay person/Public Patient Involvement absent from the workshop but involved in pre-meeting activities.

241

242 *[Please insert Figure 1 here]*

243

244 **Overall PRECIS-2 Scoring**

245 The seven team members assessed the overall design of the WCQ2 feasibility study as more
246 explanatory than pragmatic (*Figure 1, Table 1*). There were two domains with consensus: (1)
247 “Primary Outcome” and (2) “Flexibility of Adherence” (of the intervention). The Primary
248 Analysis domain was not scored by the team as that had been pre-determined as an intention-
249 to-treat analysis by previous discussions involving the WCQ2 trial statistician, and was
250 therefore deemed not relevant for the purposes of PRECIS-2. There was, however, no more
251 than one point difference in scores (out of 5) for seven domains, suggesting there was little
252 difference in rating domains. Recruitment has the widest range from “1” with an outlier of
253 “4”, with 3 scores of “1” and 3 scores of “2”.

254

255 ***Rationale of PRECIS-2 Scoring for WCQ2***

256 **Eligibility (Median Score 3):** WCQ2 trial targeted women aged over-18 in specific socio-
257 economic areas who spoke English, whereas HSE standard services typically target both men
258 and women of any age, who speak any language and live in an area in which a smoking
259 cessation officer is available.

260

261 **Recruitment (Median Score 2):** WCQ2 recruitment strategies were more diverse and
262 intense than usual HSE strategies. Local Advisory Groups (LAGs) were established in each
263 of the study areas. These included local people from the areas who would have an established
264 role in community development. The role of the LAG was to oversee WCQ2 trial conduct,
265 and to direct and deliver a local recruitment strategy. WCQ2 developed a recruitment strategy
266 and this included community stakeholders to undertake recruitment with tailor-made leaflets,
267 posters, flyers, and Facebook posts. The PI established contact with local general
268 practitioners who were encouraged to actively recruit, as were local pharmacists. There was
269 also a designated person from the ICS within each study area whose role included assisting

1 270 and coordinating recruitment. In addition, a WCQ2 trial member was assigned for
2 271 recruitment. The HSE usual recruitment routes include referral by healthcare provider, self-
3
4 272 referral, referral through a national quit team/online support, and on-going national quit
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7 273 campaigns that occur through mediums such as TV, radio, and cinema advertisements.
8
9 274 During the final wave of recruitment, an adaptation of the recruitment protocol introduced
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11 275 paid social media advertising, leaning towards a more pragmatic approach.
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17 277 **Setting (Median Score 4):** WCQ was community based, typically taking place in a
18
19 278 community centre, whereas the enhanced usual care sessions were delivered in a clinical
20
21 279 setting such as a hospital or a primary care centre. WCQ2 focussed on delivery of the
22
23 280 programme within deprived communities, and typically these areas were also within the
24
25 281 catchment areas of HSE standard services. The selection of areas within the pilot trial was
26
27 282 limited to areas where the HSE had a smoking cessation advisor available to deliver their
28
29 283 one-to-one service.
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35
36 285 **Organisation (Median Score 2):** WCQ organisation was very different from the HSE
37
38 286 standard organisation format. WCQ has been co-designed in partnership with the community.
39
40 287 The outcome of each programme was celebrated and shared with the community. Participants
41
42 288 were encouraged to share their experience with others.
43
44 289 The delivery format was group-based. WCQ offered face-to-face peer support groups for
45
46 290 women, involving trained Community Facilitators working in pairs (one was ideally an ex-
47
48 291 smoker). Many were specifically recruited for this smoking cessation programme. The
49
50 292 delivery model applied a social model of health to tobacco cessation. Community Facilitators
51
52 293 were trained in both the National Standard for Tobacco Cessation Support (NSTCS) (21) and
53
54 294 the Social Determinants of Health framework including issues of gender, income, health
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295 access, self-efficacy and educational inequality to their content and programme delivery.

296 Some were experienced group facilitators; others were also trained in group facilitation. The

297 HSE Smoking Cessation Officers are trained to offer behavioural support and advice relating

298 to quitting smoking and maintenance on a one-to-one basis. This is also based on the NSTCS.

299 Most Smoking Cessation Officers have clinical backgrounds (e.g., nursing). The HSE operate

300 a nationally available 'Quit Line' offering free telephone and text support. The control arm of

301 the trial, therefore, could be considered 'enhanced' usual care.

302

303 **Intervention flexibility delivery (Score 3):** The WCQ programme structure allowed for

304 tailoring and flexibility in programme delivery. Within the last six of 12 sessions women

305 were encouraged to choose content and activities based on a menu of locally available

306 options that they considered would be of benefit to their quit attempt (e.g., practical healthy

307 eating and physical activity workshops; additional stress management; women's health or

308 relaxation workshops etc). This degree of flexibility or choice was not available within the

309 enhanced usual care control arm. Therefore, there was variation between the intervention and

310 control arms in relation to the number, content and length of sessions. WCQ community

311 facilitators worked with pharmacists to assist women to get access to NRT. There was self-

312 monitoring by community facilitators through the use of a diary and checklist to monitor

313 treatment fidelity regarding programme delivery, which were returned to the trial team.

314

315 **Flexibility adherence (Median Score 2):** In our trial, the WCQ community facilitators used

316 verbal encouragement during the face-to-face sessions and email, text and phone support

317 between sessions to promote participation. WCQ women were never excluded if they missed

318 sessions, they were always welcome to attend. Women enrolled into WCQ were allocated a

319 designated local community pharmacist for the dispensing of their NRT. Women reported

320 that they would often seek additional support from the pharmacist between meetings.

321 Pharmacists also encouraged continuation of attendance at weekly programme meetings. In

322 the control arm women were not formally linked in with a community pharmacist.

323 An incentive of €20 voucher for completing data at the 12-week and 6-month follow-ups was
324 provided to all trial participants.

325

326 **Follow up (Median Score 2):** WCQ was longer in duration than the control arm. WCQ

327 women attended weekly sessions for 12 weeks, whereas in enhanced usual care arm women

328 were seen for between 6-8 sessions. Retention, number of sessions attended, engagement in

329 smoking cessation processes (e.g., setting a quit date) and completion of data was closely

330 monitored in each arm. Corroborated smoking abstinence rates at 12 weeks and at six months

331 were assessed. Both groups completed the 12-item Short Form Survey questionnaire (SF-12)

332 (22) to measure function and well-being status across each study data collection time point

333 (baseline, 12 weeks and six months). Qualitative interviews were conducted after week 12 in

334 the WCQ arm with intervention women and the community facilitators who delivered the

335 intervention. Community facilitators were also asked to complete measures relating to

336 acceptability, appropriateness and feasibility (23). Interviews were not conducted with

337 control arm participants.

338

339 **Primary Outcome (Score 1):** As this was a pilot and feasibility study, the main outcomes for

340 the trial were recruitment and retention as part of feasibility testing. All workshop

341 participants were in agreement that “stopping smoking” would be the very pragmatic primary

342 endpoint, scoring “5”, in the full DT, for women, for healthcare providers and from a public

343 health perspective.

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Discussion

PRECIS-2 aims to make explicit the impact that design choices will have on the relevance of trial results to the users of the results beyond trial conditions. The PRECIS-2 tool was originally designed to be used prospectively, as a planning tool for the design of RCTs. It has been also used retrospectively as a tool to assess the pragmatic or explanatory characteristics of RCTs in systematic reviews (24, 25) or to assess trials that were already in progress (18, 26). To our knowledge, this is the first study which describes the retrospective use of PRECIS-2 in a pilot cluster RCT as a part of the trial process evaluation. Our results indicated that the overall WCQ2 pilot trial design was more explanatory than pragmatic, contrary to the intended purpose of the trial. Characteristics of Recruitment, Organisation, Flexibility in Adherence, and Follow-up of the pilot study design were scored as explanatory domains, and Primary outcome as very explanatory. The setting of WCQ2 study in the community was the most pragmatic characteristic of the design. Eligibility and Flexibility in Delivery were assessed as equally pragmatic/explanatory domains.

Few pilot and feasibility studies have been published using the PRECIS-2 tool in their design. A recently published pilot trial of a surgical intervention trial, the pGO-Tibia pilot in Tanzania (27), contained both pragmatic and explanatory aspects but ultimately tended towards a pragmatic design to facilitate implementation in their chosen settings. Similar to our pilot trial, the main outcomes were recruitment and retention (28), which resulted in the Primary outcome domain assessment as very explanatory which is to be expected. In a future DT of the effectiveness of WCQ2 the primary outcome will be smoking abstinence, matching the real-world environment.

1 370 The domain matrix (*Additional File 1*) was the basis for discussion on design improvements
2 371 for the future definitive RCT. Recruitment rates were closely monitored throughout the four
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4 372 trial waves. Intense monitoring of recruitment efforts led to advancements made on the
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7 373 recruitment strategy to maximise recruitment, which resulted in this domain becoming very
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10 374 explanatory. These additional recruitment efforts, while effective and necessary to reach
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12 375 target numbers in the final recruitment wave, may have introduced a selection bias (29) in the
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14 376 eligibility criteria. A pragmatic approach would recruit women who present themselves in
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17 377 routine care to get help to stop smoking whereas WCQ2 used additional recruitment methods
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19 378 as well as encouraging participants to bring friends. We believe this was unavoidable under
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22 379 trial conditions.

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26 381 Retention was also challenging, and in a DT more intensive efforts would be required to
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29 382 assist participants to complete follow up (30). The ‘organisation’ of a DT would also require
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31 383 changes to incorporate both the community facilitators’ and researcher specific training in
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34 384 working with women who have low literacy. This was a major barrier to recruitment and
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36 385 retention in the pilot trial. More support to complete data collection and a greater adaptation
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39 386 of data forms will also be needed in a future trial. This may improve the accessibility of
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41 387 programme resources and trial documentation to the targeted groups of women who were
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44 388 trying to stop smoking. In terms of ‘Flexibility of delivery’ of the intervention, the WCQ2
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46 389 team recommended more structured contact with women between sessions. However,
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49 390 objective measurements for monitoring of the fidelity of intervention delivery would still be
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51 391 advocated.

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56 393 The WCQ2 trial team found that PRECIS-2 may be useful to capture trial design discussion
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58 394 from inception to the definitive RCT (31). The key to using PRECIS-2 was an in-depth
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1 395 knowledge of standard practice to stop smoking in Ireland; local expert knowledge was
2 396 important to complete the PRECIS-2 domains and assist the trial team to determine the gap
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4 397 between the trial intervention and usual care. For this study, which focussed on supporting
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7 398 women living in deprived areas to stop smoking, this information is critical to facilitate
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10 399 further implementation of the programme into a full-scale trial in similar areas. Lack of a
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12 400 clear description of the usual care comparator in trials has previously been highlighted (32),
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14 401 with clear reporting being encouraged to ensure adherence to the CONSORT guidelines (33,
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17 402 34). The WCQ2 team endeavoured to provide an in-depth description of both the intervention
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19 403 and the comparator, and the PRECIS-2 tool guided this information sharing. It provided a
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21 404 framework for a shared understanding amongst public health academics, health promotion
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24 405 practitioners and public/patient representatives of the key components of both interventions
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27 406 and their key differences as well as their strengths and weaknesses for their target audiences.
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31 408 We believe that a strength of this study is the detailed descriptive information from the trial
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34 409 team (*Additional file 1*) which concurs with others using the tool to assist in generalisability
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36 410 of findings (35). Our domain information, however, is specific to this WCQ2 pilot study and
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39 411 may not necessarily be generalisable to other settings. It is worth emphasising that the
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41 412 rationale behind the PRECIS-2 score is most important for implementation, rather than the
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44 413 score in itself. Our discussions also highlighted that there was an issue with enhanced usual
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46 414 smoking cessation programmes in the target areas for the HSE control arm which are not as
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49 415 yet universal across Ireland, which resulted in a lively debate on implementation during the
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51 416 pilot study.

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56 418 Two limitations are worth noting. First, the assessment of PRECIS-2 domains was completed
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58 419 by those running the trial/delivering components of the programme, therefore, there is the
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1 420 potential for assessment bias although presence of the author of PRECIS-2 (KL) who
2 421 facilitated and guided discussion may have counter-acted this. Secondly, the PRECIS-2
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4 422 assessment evaluated the fourth and final wave of the trial when recruitment challenges had
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7 423 been largely understood and ameliorated, and when the expected recruitment rate per wave
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9 424 had been achieved.

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12 426 The National Institutes of Health (NIH) Pragmatic Trials Collaborative Project in the United
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15 427 States have introduced a trial planning and implementation project in response to an NIH
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18 428 Request for Applications to fund low-cost, pragmatic, patient-centred clinical RCTs. Results
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21 429 from this project reported that PRECIS-2 was useful in “framing the conversation” about trial
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24 430 design in the conduct of the feasibility studies, and finalisation of trial protocols (36). This
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27 431 was also recently discussed by the National Institute on Aging for pilot stage clinical trials,
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29 432 which suggested that the PRECIS-2 tool could be used to optimise recruitment strategies,
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31 433 intervention flexibility and adherence measures in embedded pragmatic clinical trials , testing
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33 434 interventions to help elderly dementia patients in real-world settings (37). The current WCQ2
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36 435 project concurs with that assessment but also found PRECIS-2 useful for all domains
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39 436 assessed.

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43 438 The learning points from applying PRECIS-2 to the WCQ2 trial may be useful for other
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46 439 researchers planning to conduct future trials. We believe that widening the circle of
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49 440 participants using PRECIS-2 to include all members of trials teams (new and experienced
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51 441 trialists) would facilitate discussion of all aspects of the design of a pilot RCT. Participation
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53 442 might include greater involvement of patient/public representatives (with appropriate
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56 443 training) and involvement of the steering group to bring richer perspectives from informed
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58 444 voices who have a thorough understanding of trial process rather than relying fully on the
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5 445 scores. While PRECIS-2 was only used after the fourth wave of recruitment in our pilot RCT,
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7 446 we believe it might also have been helpful to inform each wave in a dynamic iterative way
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9 447 and to inform adaptive trial designs.
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14 449 Our findings provide further insight to assist trial teams in designing future trials of complex
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16 450 health promotion interventions in community settings and the learning from applying the
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18 451 PRECIS-2 tools to the findings of pilot and feasibility trials. To this end, PRECIS-2 should
19
20 452 be applied in advance of DT design to open up discussions on the implementation of complex
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22 453 trials in community settings. This important assessment stage could prevent problems and
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24 454 avoid clinical trial research waste (see <http://researchwaste.net>).
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29 457 **Conclusions**

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31 458 PRECIS-2 enabled meaningful discussion within the trial team of the key elements of a future
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33 459 definitive intervention trial design, thereby improving our understanding of the applicability
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35 460 of trial results to assist women in deprived areas in Ireland to stop smoking. In particular, it
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37 461 helped the trialists consider the consequences of design decisions for WCQ2 and the gap
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39 462 between the WCQ intervention and the enhanced usual care control arm for smoking
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41 463 cessation provided by the HSE. PRECIS-2 was an important tool to support the decision on
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43 464 whether to undertake a full trial but only as part of the overall assessment, which included
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45 465 quantitative indicators of the direction of effect as well as the qualitative findings from the
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47 466 process evaluation, all three supported this decision.
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55 469 **List of abbreviations**

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470 NRT= Nicotine replacement therapy
471 WCQ= We Can Quit
472 SED= socioeconomically disadvantaged
473 ICS= Irish Cancer Society
474 HSE= Health Service Executive
475 RCT= randomised controlled trial
476 WCQ2= We Can Quit2
477 PRECIS-2= Pragmatic Explanatory Continuum Indicator Summary
478 PI= Principal Investigator
479 LAGs= Local Advisory Groups
480 NSTCS= National Standard for Tobacco Cessation Support
481 SF-12= 12-item Short Form Survey questionnaire
482 NIH= National Institutes of Health.
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485 **Declarations**

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486 **Ethics approval.** The study was approved by the School of Medicine Research Ethics
487 Committee, Trinity College Dublin (Reference number: 20170404).
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489 **Consent for publication.** Not applicable.

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490
491 **Availability of data and materials.** The dataset (descriptions of the WCQ2 trial arms, the
492 HSE standard smoking cessation services, and the scoring rationale for each domain used to
493 apply the PRECIS-2 tool) are included within the article and its Additional file 1.

1
2 495 **Competing interests.** CBH reports grants from HRB and Enterprise Ireland during the
3 496 conduct of the study. CD reports grants from HRB during the conduct of the study.

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5 497
6
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8
9 499 Interventions and Feasibility Awards DIFA-2017-048.

10 500
11
12 501 **Authors contributions.** CD led the design and analysis of the trial process evaluation. KL
13
14 502 provided guidance in the use of PRECIS-2, facilitated the workshop conduct and prepared the
15
16 503 PRECIS2 wheel. CD, KL, NOC, EB, JV, CR, AB, PW and CBH conducted the PRECIS-2
17
18 504 analysis. CBH obtained funding and led the design of the trial, with contributions and advice
19
20 505 from ND, LB, CD, JV (co-investigators), KL, CD drafted the paper with critical input from
21
22 506 CBH and all other authors.

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24 507
25
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29
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31
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33
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37
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39
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41
42 516 Clinical Research Foundation in particular Fergal Seaballuck who performed the
43
44 517 randomisation.

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17 634 **Figure caption**

18 635 **Figure 1:** Composite score PRECIS-2 wheel for seven WCQ2 team members.
19 636

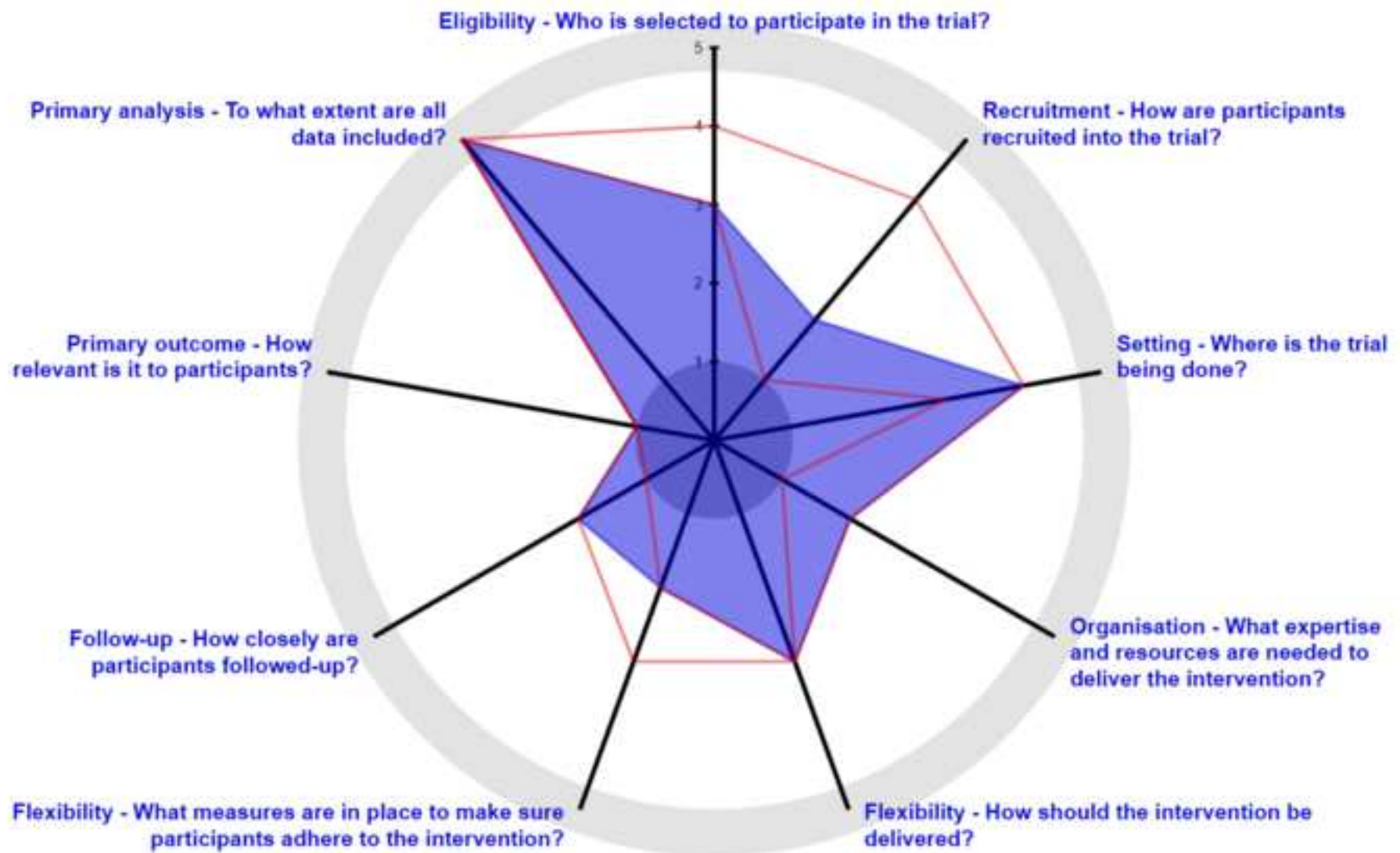
20 637 **Additional material**

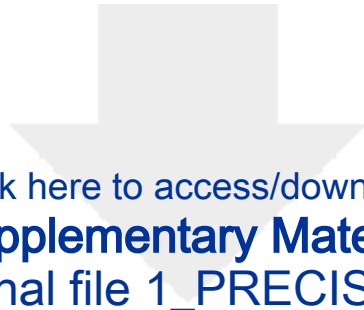
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23 640 Title of data: PRECIS-2 scores for WCQ (intervention) versus HSE usual care (control).
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25 642 Description of data: Scores for WCQ intervention and HSE usual care treatments, compared
26 643 to the WCQ2 trial treatments.
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Supplementary Material
Additional file 1_PRECIS-2.docx





CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	4-6
	2b	Specific objectives or research questions for pilot trial	6
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	N/A
	4b	Settings and locations where the data were collected	N/A
	4c	How participants were identified and consented	N/A
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	N/A
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	8-10
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	N/A
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size	7a	Rationale for numbers in the pilot trial	N/A
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	N/A
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	N/A
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	N/A

concealment mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	7-10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	10
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	N/A
	14b	Why the pilot trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	N/A
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	N/A
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	10-14
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
	19a	If relevant, other important unintended consequences	N/A
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	17-18
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	18-19
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	15-17
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	15-19
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	3
Protocol	24	Where the pilot trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	21

	26	Ethical approval or approval by research review committee, confirmed with reference number	20
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Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
