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Pilot and Feasibility Studies

Muslim Communities Learning About Second-hand Smoke in Bangladesh (MCLASSII): a combined evidence and theory-based plus partnership intervention development approach.

--Manuscript Draft--

Manuscript Number:	PAFS-D-21-00349R1	
Full Title:	Muslim Communities Learning About Second-hand Smoke in Bangladesh (MCLASSII): a combined evidence and theory-based plus partnership intervention development approach.	
Article Type:	Research	
Funding Information:	Medical Research Council (MR/P008941/1)	Professor Kamran Siddiqi
Abstract:	<p>Abstract</p> <p>Introduction</p> <p>Deaths from second-hand smoke (SHS) exposure are increasing but there is not sufficient evidence to recommend a particular SHS intervention or intervention development approach. Despite the available guidance on intervention reporting, and on the role and nature of pilot and feasibility studies, partial reporting of SHS interventions is common. The decision-making while developing such interventions is often under-reported. This paper describes the processes and decisions employed during transitioning from the aim of adapting an existing mosque-based intervention focused on public health messages, to the development of the content of novel community-based Smoke-Free Home (SFH) intervention. The intervention aims to promote smoke-free homes to reduce non-smokers' exposure to SHS in the home via faith-based messages.</p> <p>Methods</p> <p>The development of the SFH intervention had four sequential phases: in-depth interviews with adults in households in Dhaka; identification of an intervention programme theory and content with Islamic scholars from the Bangladesh Islamic Foundation (BIF); user testing of candidate intervention content with adults, and iterative intervention development workshops with Imams and khatibs who trained at the BIF.</p> <p>Results</p> <p>It was judged inappropriate to take an intervention adaptation approach. Following the identification of an intervention programme theory and collaborating with stakeholders in an iterative and collaborative process to identify barriers, six potentially modifiable constructs were identified. These were targeted with a series of behaviour change techniques operationalised as Quranic verses with associated health messages to be used as the basis for Khutbahs. Following iterative user testing, acceptable intervention content was generated.</p> <p>Conclusion</p> <p>The potential of this community-based intervention to reduce SHS exposure at home and improve lung health among non-smokers in Bangladesh is the result of an iterative and collaborative process. It is the result of the integration of behaviour change evidence and theory, and community stakeholder contributions to the production of the intervention content. This novel combination of intervention development frameworks demonstrates a flexible approach that could provide insights for intervention development in related contexts.</p>	
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	Kamran Siddiqi, PhD
Order of Authors Secondary Information:	
Response to Reviewers:	<p>Response to the editor's comments:</p> <p>[ec1] Page 7, Table 1: remove table 1, and replace it with a summary characteristics table which shows numbers and % of male and females, smoker status and etc... We have made this change.</p> <p>[ec2]. Page 8, first sentence: Nor clear, rephrase this sentence We have corrected this line, which now reads "The basis for the programme theory to guide the development of the content targeting SFH was planned to be selected following the face-to-face interviews."</p> <p>[ec3]. Page 8, first paragraph, last sentence:add a full stop please. We have made this change.</p> <p>[ec4]. Table 2 and 2: remove table 2 and 3, and replace these with a summary characteristics table which shows numbers and %s We have made changes to both 2 and 3</p> <p>[ec5]. Page 15: provide a summary of what figure 1 is demonstrating in text in the body of the manuscript. it is not clear We have now clarified the role of the programme theory represented in figure 1 in the following paragraph: Based on the evidence of the previous utility of the model for understanding and intervening on smoking behaviour [42, 43] we selected the Theory of Planned Behaviour, extended with action planning and coping planning as the starting basis for the programme theory to guide the development of the intervention content (see Figure 1) targeting SHS. The constructs we sought to operationalise drawn from this model were Attitude, Social Norms, Intention formation, Self-efficacy, Action Planning, Coping planning. Using the interview findings and the selected constructs from the programme theory, a Muslim colleague with knowledge of social cognitive constructs and the BCT taxonomy [39] supplied a list of ayahs that could support messages to promote change in these potentially modifiable constructs that were identified as being present within the interview. We mapped the programme theory constructs findings were then mapped to BCTs [39] that seemed likely to result in changes in those constructs based on study team expertise, and subsequently result in change in air quality (AQ) and smoke-free home (SFH) status. The list of ayahs, the constructs targeted, the health messages, and the BCTs the health messages were mapped to is contained in Table 4.</p> <p>Response to reviewer 1 comments: [r1.1]: This paper describes the development of an intervention to promote smoke-free homes via faith-based messages in Bangladesh. This is well-designed and conducted study and the manuscript is well-written. I have only minor comments: Abstract: The results section does not currently mirror the results within the full body of the text and could be improved. We thank reviewer 1 for the kind comment. We have sought to further detail the results section of the abstract to align it with the</p>

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We have deleted this repetition.

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Response to reviewer 2 comments:

[r2.1] Reviewer #2: The title encapsulate the research well and contains all necessary keywords. the study objectives and importance are stated and convincingly motivated. The literature review is done in depth and provide necessary information for the reader to understand the goal of the paper. The research methods is appropriate for the paper. The population in all the phases is clearly identified.
We thank reviewer 2 for the kind comments.

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Suggested Reviewers:	
Additional Information:	
Question	Response
<p>Declarations</p> <p>Have you included a 'Declarations' section in your manuscript including all of the subheadings listed below and the relevant information under each?</p> <ul style="list-style-type: none"> Ethics approval and consent to participate Consent for publication Availability of data and material Competing interests Funding Authors' contributions Acknowledgements <p>Click here for information on what should be included under each heading.</p> <p>Please use the 'Contact Us' link above if you require further assistance</p>	<p>I confirm I have provided a complete 'Declarations' section in my manuscript</p>
<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>	<p>No</p>

Dr Ian Kellar

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27/09/2021

Dear Vichithranie Wasantha Madurasinghe

I am pleased to respond to the editor's and reviewers' comments on "Muslim Communities Learning About Second-hand Smoke in Bangladesh (MCLASS II): a combined evidence and theory-based plus partnership intervention development approach. We were delighted with the decision of Minor Revision. However, we welcomed the kind and thoughtful comments, and have revised the manuscript (tracked changes accepted submitted, tracked changes version available) accordingly. Please see the following point by point comments.

Sincerely,

Ian Kellar, DPhil

Associate Professor of Health Psychology

University of Leeds

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2 combined evidence and theory-based plus partnership intervention development approach.

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43 23
44
45 24 **Word count: 5293**

46
47 25
48
49 26 **Abstract**

27 Introduction

28 Deaths from second-hand smoke (SHS) exposure are increasing but there is not sufficient evidence
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39 The development of the SFH intervention had four sequential phases: in-depth interviews with
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54 The potential of this community-based intervention to reduce SHS exposure at home and improve
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61 **Funding**

62 Medical Research Council UK under the Global Alliance for Chronic Diseases research programme.
63 Grant number MR/P008941/1.

65 **Keywords**

66 smoke-free home, mosque, intervention development

68 **INTRODUCTION**

69 Historically, behaviour change intervention content is under-reported [1], impacting replicability,
70 subsequent development, and scalability. A recent review of second-hand smoke (SHS) intervention
71 studies [2] indicated that partial reporting of SHS interventions is common. It was recommended
72 that intervention reporting guidelines are adhered to and that comprehensive reporting of
73 behaviour change techniques (BCTs) and the provision of a logic model linking BCTs to the
74 intervention theory of change is mandated. The need to be pragmatic in resource-limited contexts is
75 common in intervention development [3]. The decisions taken in these contexts and elsewhere may
76 enlighten those seeking to understand what leads to successful intervention development. A range
77 of theoretical models and intervention development approaches to protect children from SHS [4]
78 have been proposed, but recent reviews of smoke-free homes (SFH) [5, 6] and of SHS interventions

for children [7] have not provided the basis for specific recommendations. Hoddinott [8] suggests that a greater understanding of the effectiveness of interventions will result from transparent reporting of how stakeholder groups are involved in decision-making during the development of complex interventions. This paper describes the process of developing the content of a novel mosque-based smoke-free home (SFH) intervention in Bangladesh that has subsequently been trialled [9].

Key messages regarding feasibility

1) Previous work had identified concerns around the feasibility of developing smoke free homes messages that could be delivered in mosques.

2) Our approach demonstrates it is feasible to develop explicitly faith-based messages for use in mosques by working iteratively with stakeholder groups from religious communities.

3) The reported intervention development utilised a 4-phase process for working with stakeholders from religious communities to develop faith-based intervention content.

Background

SHS is the combination of emissions of smoke emitted between a puff of lit tobacco and the smoke that is exhaled by smokers [10]. Children's risks from asthma [11], acquiring lower respiratory tract infections, [12, 13] and tuberculosis [14, 15] are all increased by exposure to SHS. Children living in smoking households are also at high risk of becoming adult smokers later [16]. Childhood exposure to SHS is strongly associated with the prevalence of adult smoking [17].

Whilst between 1990 and 2006, the estimated number of deaths attributed to SHS fell, it has subsequently increased, driven by increases in SHS exposure in South Asia, East Asia and the Pacific [18]. The WHO estimates that 1.2 million deaths per year are attributable to non-smokers being exposed to SHS [19]. This research focuses on a settings-based approach [20], focussing on

engendering a health-supporting environment [21] to protect non-smoking adults and children from the harms of SHS in their homes. There have been calls for research into the efficacy of health interventions that are delivered by Imams or in mosques [22, 23]. The work builds on the findings of a pilot trial conducted in England which concluded that an SFH intervention was acceptable to Muslim communities and feasible to deliver in mosques [24]. In the present work, the intervention development explicitly aimed to result in faith-based material directly targeted at smokers via faith leaders based in mosques (Imams and khatibs) for the planned trial [25](MRC RGMR/P008941/1).

METHODS

Development approach

The starting point of the intervention development approach was material arising from the UK-based MCLASS trial [26], for which a package of SFH materials was developed that drew upon consensus around the religious prohibition of the use of tobacco products among Muslims [27, 28], and evidence that a complex intervention that included a mosque-based component had promising effects on SFH prevalence [29]. The MCLASS intervention took a settings-based approach, seeking to support health-promoting environments. The intervention was tailored to the cultural values of the target population: South-Asian men ill-served by smoking cessation services that don't address cultural sensitivities [30-32]. Relatively few faith setting-based interventions have been developed for mosques [33].

A recent UK Medical Research Council (MRC)-funded project has produced a taxonomy of intervention development approaches for complex interventions [34]. This specified eight categories: partnership, target population-centred, evidence and theory-based, implementation-based, efficiency-based, stepped or phased-based intervention specific, and combination. Our development work does not fit neatly into this taxonomy, in that we had previously undertaken SHS intervention development in the UK [26]. We initially expected to undertake an intervention

adaptation approach using the Programme Theory of Adapted Health Interventions [35] making use of the UK-based MCLASS trial materials [26]. However, subsequent process evaluation of the existing intervention [24] raised issues around the acceptability of religious teachers taking on a health promotion role, and it was reported that some participants were unhappy that the mosque was being used as a context for delivering health promotion messages:

“When you come to the mosque, you want to pray, you know? And [its’] a place of worship really. And you don’t want to come here and do other things you know? You want to escape from these things you see.” (FGD-Men)(p.300)

We subsequently looked to ayah (Quranic verse) for messages that supported SFH so that the messages were drawn from the Quran and would not be jarring for worshippers or out of place in mosques. Given the limited expertise of we in the Quranic scripture, it was felt important to undertake an intervention development process that examined the wider context of smoking and SFH, and following content development, put this before stakeholder groups in Bangladesh for iteration, including those with a scholarly understanding of Quranic scripture.

We elected to undertake a development process that consisted of four phases:

- 1) Interviews exploring barriers and facilitators of SFH with adults from locations near the planned recruitment sites.
- 2) Identification of an intervention programme theory and content with Islamic scholars from the Bangladesh Islamic Foundation (BIF) with expertise in Quranic scripture to identify candidate content
- 3) User testing of candidate intervention content with adults.
- 4) Iterative intervention development workshops with Imams and khatibs.

Phase 1 - Interviews exploring barriers and facilitators of SFH

Face-to-face interviews were conducted from May to July 2017 in the Mirpur and Gulshan regions of Dhaka city with six men and two women (see Table 1).

Table 1: Interview participant characteristics. (n=8)

Characteristic		Number	%
Sex	Male	6	75
	Female	2	24
Smoking status	Smoker	6	75
	Non-smoker	2	25
Age	30-39 years	4	50
	40-49 years	4	50
Education	None/Primary	4	40
	Secondary	2	25
	Honours and above	2	25

Drawing upon prior work [36-38] and a relevant systematic review and thematic synthesis [39], a semi-structured interview schedule that explored smoking behaviours, and barriers and facilitators to an SFH intervention delivered within mosques by Imams was developed. Given the aforementioned process evaluation [24] had identified issues around the acceptability and feasibility of the use of mosques to disseminate SHS messages, we took this opportunity to elicit opinions on this. Interviews lasted between 23 and 48 minutes. They were audio-recorded and fully transcribed then translated from Bangla to English. The interview data were then analysed using deductive content analysis [40]. First a categorisation matrix was developed based on the interview schedule, piloted with one transcript, and set up in Excel. The data were coded to the matrix, and then each category e.g. smoking behaviours was written up.

173

174 **Phase 2 - Identification of programme theory and content**

175 The basis for the programme theory to guide the development of the content targeting SFH was
 176 planned to be selected following the face-to-face interviews. The aim was to identify evidence-based
 177 modifiable constructs present within the interview findings and map these to BCTs [41] that seemed
 178 likely to result in changes in those constructs based on study team expertise. These BCTs were then
 179 operationalised as intervention content with the support of Quranic verses (ayahs) and linked health
 180 messages. To seed the programme content design process, we sought advice from a Muslim
 181 colleague with knowledge of social cognitive constructs and the BCT taxonomy [41] as to relevant
 182 ayahs that supported health messages that could operate as the basis for BCTs. These were fed into
 183 the Arabic Quranic Search Tool, which is a semantic search tool for the Quran based on a Quranic
 184 ontology [42] to identify a long list of ayahs which matched related concepts. To select from these
 185 ayahs and messages, we collaborated with Islamic Scholars from the Bangladesh Islamic Foundation,
 186 a government organization under the Ministry of Religious Affairs in Bangladesh whose role is to
 187 spread the values and ideals of Islam among people. The long list of ayahs was screened for those
 188 that mapped on to social cognitive constructs within our intervention programme theory. As such,
 189 these were ayahs that would support health messages that function as BCTs or prompts to perform
 190 BCTs that would potentially result in changes to the intervention programme theory constructs.
 191 Subsequently, these ayahs were then expanded upon into statements that could form the suggested
 192 basis for a Khutbah (sermon) - the time before Arabic Khutbah during Friday Jumu'ah prayers. The
 193 health messages connected ayahs to personal implications for individuals' faith and tobacco use.

194

195 **Phase 3 - User testing of candidate intervention content**

196 To test the understanding and acceptability of the selected ayahs and health messages, we
 197 employed a user testing methodology [43] using face-to-face interviews. This occurred between
 198 September and November 2017 in the Mirpur region of Dhaka. All 12 ayahs and associated health

messages were tested with a small sample of men and women (n=6, see Table 2) within the communities where we planned to trial the intervention.

Table 2: User testing participant characteristics. (n=6)

Characteristic		Number	%
Sex	Male	5	83
	Female	1	17
Smoking status	Smoker	3	50
	Non-smoker	3	50
Age	20-29 years	4	66
	30-39 years	2	33
Education	None/Primary	2	33
	Secondary	2	33
	Honours and above	2	33

For each pair of ayah and health messages, the researcher read out the ayah and asked the participant what this meant to them. The health message was subsequently read to them, and questions probing their understanding were asked, including how the message linked to the ayah. Feedback on the clarity of wording and suggestions for improvement were also sought. Interviews lasted between 40 and 70 minutes. Data analysis was as described in Phase 1.

Phase 4 - Iterative intervention development workshops with Imams and khatibs

The iterative workshops were undertaken in two sessions (labelled A and B) with Imams/khatibs from 12 mosques (see Table 3). Imams are those who lead everyday prayers in the mosques. Khatib or khateeb are those who deliver Khutbah and lead the Friday prayers. All of the Imams/khatibs

were attendees of the Imam Training Academy, Bangladeshi Islamic Foundation, part of the Ministry of Religious Affairs.

Table

3: Imam participant characteristics. (n=13)

Characteristic		Number	%
Mosque	A	6	46
	B	7	54
Role in mosque	Imam	4	31
	Mix of roles	9	69
Years of service in mosque	<10 years	5	38
	11-20 years	8	62

We employed the same user-testing methodology applied in Phase 3 [43] Experience of, and views on, delivering health and behaviour change messages within their religious teaching were also discussed. The two workshops lasted 180 minutes each. Data analysis was as described in Phase 1.

RESULTS

Phase 1 - Interviews exploring barriers and facilitators of SFH

Smoking behaviours

There was typically one smoker in each participant's home, often the interview participants themselves. The number of times they smoked in the home ranged from one to eight times a day, usually in the morning and at night, during the day the men were out at work. Some said that they try to smoke on the balcony or in an empty room, which was difficult for the three families who live together in one room. Only one smoker claimed to never smoke in the home.

233

234 *"I felt that the smoke will be harmful for my family members and I stopped smoking inside home."*

235 (P01: Male, 35 years, Smoker, highly educated)

236

237 ***Barriers and drivers to achieving an SFH***

238 Whilst all interview participants knew of the risks of smoking to the smoker, knowledge of the

239 dangers of SHS varied and was better amongst the more educated, although they still

240 underestimated the extent of potential harm.

241

242 *"I know that it harms equally others who are around someone who is smoking. That is why I have*

243 *quit smoking at home totally now."*

244 (P01: Male, 35 years, Smoker, highly educated)

245

246 The consensus was there were no disadvantages of having an SFH. Participants identified multiple

247 benefits, mentioning particularly the positive impact on the health of family members, especially

248 children. Indeed, this was seen to be the key motivator. Other benefits were seen to be eliminating

249 the smell and improving air quality in the home, reducing the risk of an accidental fire and sons not

250 copying their father's smoking behaviour.

251

252 *"Everyone loves their children. People would be ready to do anything for the betterment of their*

253 *children. If they stop smoking at home then the air of that house would not be polluted. Wives and*

254 *children of smokers will be able to inhale clean air and they will remain healthy. There would not be*

255 *any bad smell of cigarette smoke in clothing. The overall environment of home will remain very*

256 *good."*

257 (P07: Male, 36 years, Smoker, moderately educated)

258

259 The key challenge to achieving an SFH was smokers ignoring requests to smoke outside the home.

260 Several men acknowledged this, whilst one woman spoke of how it would be difficult for women to
 261 ask men to smoke outside, suggesting they may not listen or worse, react angrily. She hoped the
 262 men would be motivated themselves.

263

264 *"She tells me not to smoke inside home, she has told me. Then, sometimes, I stop smoking inside
 265 home, then maybe after a few days, I start smoking in the home again, you know."*

266 (P07: Male, 38 years, Smoker, not educated)

267

268 *"Motivating and convincing the smokers would be a challenge, I think. As in our society men are
 269 often dominating, it is not likely that all of them will listen, some of them may get angry hearing such
 270 things. In some families there might be conflict. If the smokers are motivated enough by themselves,
 271 it would be better."*

272 (P08: Female, 45 years, Non-smoker, highly educated)

273

274 ***Acceptability and feasibility of a mosque-based SHS intervention***

275 All the interview participants thought it was a good idea to educate people about SHS through
 276 mosques; because of the credibility and influence of the Imam as a religious leader, and the mix of
 277 people who would hear the messages. Most had not heard health messages in the mosque before.

278

279 *"Those who have faith in religion go to the mosque, that's why normally they should abide by the
 280 rules and regulations of the religion. As the Imam is a religious leader, people listen to him and
 281 discuss problems with him, if he talks about smoking, some people will definitely listen to those
 282 messages."*

283 (P01: Male, 35 years, Smoker, highly educated)

284

"People who go to the mosque regularly and on time are mostly guardians from families, the young generation like us are less in number. So, by them (these guardians) these kinds of messages can spread to others. Another thing would be best if we can make women in our homes more aware and they will definitely be able to make sure that nobody smokes at home."

(P06: Male, 34 years, Smoker, moderately educated)

The consensus was that the content of the messages would need to be tailored to the audience.

Women and children would need knowledge about SHS to persuade family members not to smoke inside, and to protect themselves from smoke. Whereas the men would benefit from learning about SHS in the context of Islamic scripture.

"Women also need awareness. They will then tell the smoker family members not to smoke inside home. If children get to know the harms of SHS they would then try to protect themselves from second-hand smoking."

(P07: Male, 38 years, Smoker, not educated)

"The messages should vary. In the mosque the Imam can tell people about these (messages) with hadiths and Quran teachings. But for women there can be other things. For children the message should be in such form that they can communicate with their parents."

(P02: Male, 40 years, Smoker, limited ability to read)

In terms of feasibility, the time before Arabic Khutbah (when the largest proportion of a mosque's congregation attends) was seen as the sensible time to deliver the messages as most men attend then, thus maximising the size of the audience.

310 *"We, poor people, rich people, everybody goes to Jum'ah prayer. It's like the Eid day. Old people,*
 311 *younger people, small children gather together. So, it would be good delivering these messages*
 312 *during Jum'ah prayer. Everybody will listen and give importance."*

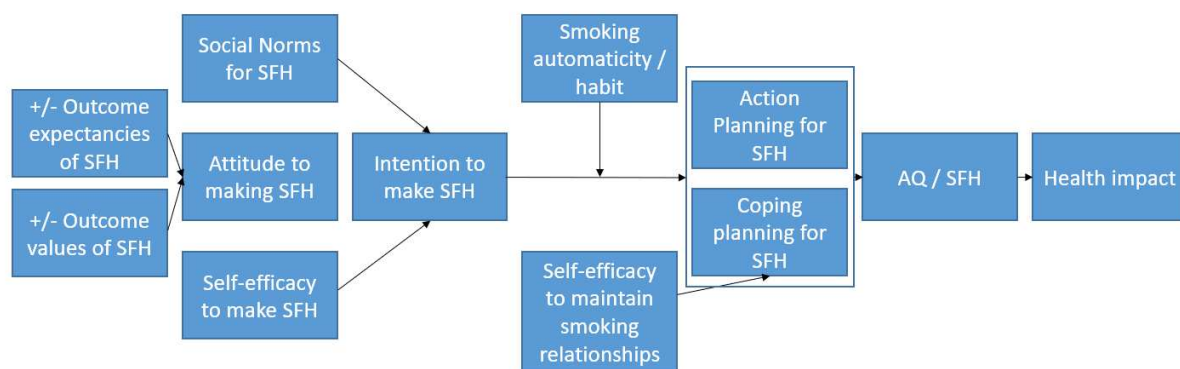
313 (P05: Female, 42 years, Smoker, not educated)

314
 315 Other ideas for message delivery were Quran classes (for children), Madrasa classes and other
 316 congregations like Milad mahfil (a custom practised by many Muslims as an expression of reverence
 317 for Prophet Muhammad (PBUH)) and Waz mahfil (Islamic sermon in the communities) although
 318 these were acknowledged to reach fewer people and occur less frequently.

320 **Phase 2 - Identification of programme theory and content**

321 Based on the evidence of the previous utility of the model for understanding and intervening on
 322 smoking behaviour [44, 45] we selected the Theory of Planned Behaviour, extended with action
 323 planning and coping planning as the starting basis for the programme theory to guide the
 324 development of the intervention content (see Figure 1) targeting SHS. The constructs we sought to
 325 operationalise drawn from this model were Attitude, Social Norms, Intention formation, Self-
 326 efficacy, Action Planning, Coping planning. Using the interview findings and the selected constructs
 327 from the programme theory, a Muslim colleague with knowledge of social cognitive constructs and
 328 the BCT taxonomy [41] supplied a list of ayahs that could support messages to promote change in
 329 these potentially modifiable constructs that were identified as being present within the interview.
 330 The programme theory constructs findings were then mapped to BCTs [41] that seemed likely to
 331 result in changes in those constructs based on study team expertise, and subsequently result in
 332 change in air quality (AQ) and smoke-free home (SFH) status. The list of ayahs, the constructs
 333 targeted, the health messages, and the BCTs the health messages were mapped to is contained in
 334 Table 4.

335 **Figure 1: Intervention programme theory**



(insert) Table 4: Initial ayahs, constructs, messages and coded BCTs

Phase 3 - User testing of candidate intervention content Results

All participants understood the general meaning of the ayahs and the health messages as well as the links between the two. Small edits to the precise wording of some of the public health messages were made, to improve comprehension; for example, for the message linked to Ayah Sura At-Takaathur (see Table 4, ayah 4) the concept of “worldly pleasure” was unclear to some leading to a suggestion to reword this. No major changes were deemed necessary at this stage.

Phase 4 - Iterative intervention development workshops with Imams and khatibs *Imams' experience and views of delivering health promotion messages*

There was a view amongst the Imams that they talk about health-related issues in the mosques only when directly relevant to religion, for example, addiction to smoking or alcohol or eating good foods; or when prompted by a current public health issue such as an outbreak of disease where they may advise on disease prevention strategies.

353 *"Addiction and smoking are sometimes discussed in mosques because it is destroying our children*

354 *and adults, taking them away from Allah. There are young people who are always behaving badly to*

355 *their parents. They are acting unaware of the consequences both in this world and the hereafter."*

356 (B07: Imam, khatib and Principal)

357

358 *"Allah has even told us to eat pleasant foods... Drugs, smoking, these are already Haram by Allah's*

359 *law and moreover there are unpalatable, stinky food, which is why these are harmful for health."*

360 (A06: Imam)

361

362 *"A few days ago, city corporation people came to us and told us to talk on Chikungunya in Jumu'ah*

363 *prayers. So, we did this."*

364 (B03: Imam and khatib)

365

366 The exception was during Ramadan when there is more emphasis on changing people's "bad"

367 behaviours and helping them to focus more on praying to Allah.

368 They were generally motivated to deliver health messages in mosques and familiar with including

369 messages during Khutbah in Jumu'ah prayer about behaviours that harm people both physically and

370 spiritually. Educating men about the risks of smoking and SHS was seen as a good idea, particularly

371 as people rarely learn about SHS, so the intervention was considered to represent an opportunity,

372 with the input of international researchers seen as an asset. Additionally, this perceived scientific

373 foundation of the intervention was seen as important as Imams did not consider themselves experts
 374 on public health, rather their expertise was in spiritual matters.

375

376 *"Actually, you have to pray to Allah from Dunya (this world). After death, there is no chance for*
 377 *earning good deeds. So, for earning good deeds, the first condition is Haya (life). Abstaining from*
 378 *addiction what Allah prohibited and what the prophet (PBUH) did and encouraged us to do, if we*
 379 *follow those, the Hayat will increase."*

380 (A01: Imam)

381

382 *"If we can tell them about some medical facts on smoking along with religious messages on it, they*
 383 *will be more aware of it."*

384 (B04: Imam)

385

386 *"We have both indirect and direct smoking here which is very bad. People do not hear much about*
 387 *second-hand smoking from anyone I guess."*

388 (B02: Iman and Teacher)

389

390 *"So, if we get a booklet or guideline including information on medical science, and if the messages*
 391 *are included by studying Quran and Hadith, then these will be more acceptable. People will*
 392 *understand that not only Imams know about Quran and Hadiths but also are knowledgeable of other*
 393 *fields."*

394 *(A02: Iman and khatib)*

395

396 They were also happy to deliver messages about planning, attempting and failing to change

397 behaviours, observing that people are used to this, and Islam teaches them how to face such

398 situations, with Imams seen as a trusted source of support.

399

400 *"I think this is a great opportunity for Imams and common people because thousands of people can*

401 *be reached with these messages and thus, Imams can make more people aware."* (A05: Imam and

402 khatib)

403

404 Jumu'ah prayers on Fridays was seen as the most appropriate time to deliver the messages, as this is

405 when there are large numbers of people in the mosque, and they have time to elaborate on the

406 meaning. There was a view amongst some that it would be important to deliver a message one

407 week, discuss it the next week and then return to it several weeks later as a reminder.

408

409 ***Feedback on ayahs and health messages***

410 Imams were keen to undertake a careful check of the selected ayahs and proposed links with health

411 messages. Some wanted more time outside of the workshop to do this work; whilst others advised

412 that alims (Islamic scholars) should review the final list of ayahs and associated health messages.

413 There was agreement that the same ayahs and linked public health messages were appropriate for

414 all mosques. The Imams' suggestions for the 12 ayahs (listed in Table 4) are summarised below. The

consensus across both workshops was that ayahs 3, 5, 7, 9, 12 were appropriate; and that ayah 4 was not suitably linked to the public message, although no one had an idea for a replacement. For the others, suggestions for alternatives were offered. These were usually to avoid misinterpretation or strengthen the take-home message. For two ayahs, changes were proposed to correct the meaning in the context of Islamic scripture.

Ayahs 1 and 10 were considered by some Imams to be open to misinterpretation. For Ayah 1, there was some concern that people might think that smoking is beneficial. Ayah 10 was seen as confusing about the type of knowledge being referred to; it should be understood to be knowledge of religion not knowledge of the harms of SFH. For ayahs 6 and 12, some Imams wanted to strengthen the message about the forgiveness of Allah. Alternatives for ayah 8 were offered to further encourage people to change their smoking and second-hand smoke behaviours by emphasising the importance of following the life and guidance of the prophet.

The two ayahs that were questioned in terms of religious accuracy were 2 and 11. For ayah 2 precision was needed that it is the Imam (not the scientist) who has authority to advise on what harms and heals to be consistent with the laws of Shariah. For ayah 11, the selected ayah was referring to divorce hence inappropriate.

As a result of the workshops, half the Ayahs were replaced with different Ayahs that better conveyed the messages or were more closely related to the public health messages targeted to be delivered. Ayah 1, 6, 8, 10, 11 and 12 were changed. Ayah 1, 8, 10, 11 and 12 were replaced with Ayahs suggested by the scholars of the Islamic Foundation, Bangladesh and Ayah 6 was replaced with another Ayah chosen by ARK researchers (see Table columns 6 & 7).

Format of the intervention content

The final version of the intervention was formatted as a booklet for Imams that contained the Arabic ayah, a translation into Bangla, and the related health message (see figure 2 for examples translated into English).

Figure 2. Examples of pages of the intervention booklet (translated into English)



The intervention booklet finally contained 12 ayah and related health messages in total (see table 1 columns 6 & 7). Training on delivery of the Intervention was provided over a half-day and was supported by a training manual. Training materials are available at [\[https://www.york.ac.uk/healthsciences/research/public-health/projects/mclass11/#tab-3\]](https://www.york.ac.uk/healthsciences/research/public-health/projects/mclass11/#tab-3). Imams or khatibs in the mosques that were randomised to deliver the SFH intervention received copies of the intervention booklet to distribute to their congregation members after Friday Jumu'ah prayers or in study circles. Intervention delivery started immediately after training and continued for 12 weeks. Full details of the trial procedures have been previously published [9].

451

452 **DISCUSSION**

453 The intervention development process reported here primarily took an evidence and theory-based
 454 approach [34], based on the MRC Framework [46, 47], in common with multiple approaches to
 455 intervention development [48]. Additionally, we took a partnership approach and engaged with
 456 stakeholder groups to both generate ideas about components and features of the intervention [49]
 457 and make decisions about the content, format and delivery of the intervention [48]. As such, this
 458 was a combination approach to intervention development [34].

459

460 **Summary of this approach**

461 In accordance with MRC guidance [46], considerable resources were invested to develop an
 462 intervention with a conceivable intervention effect on SFHs. This process benefitted from
 463 intervention development that had previously been undertaken as part of the UK MCLASS trial [1,
 464 24, 26], as well as intervention development work that preceded this [29]. The four phases
 465 undertaken were resource consuming. However each phase either directly or indirectly supported
 466 the creation or adaption of intervention content, with interviews exploring barriers and facilitators
 467 of SFH with adults, subsequent identification of an intervention programme theory and population
 468 of initial content with Quranic scripture, user testing of candidate intervention content with adults
 469 that resulted in minor changes to aid understanding, and iterative intervention development
 470 workshops with Imams and khatibs that resulted in major changes to the content to better reflect
 471 Islamic scholarship. The paucity of evidence as to effective SFH interventions [5, 6], and the
 472 previously highlighted concerns about intervention content [24], provided the impetus to
 473 appropriately support engagement with stakeholders to understand the religious and socio-cultural
 474 sensitivities of promoting SFH in a mosque setting [30, 50]. This approach reflects calls to
 475 conceptualise stakeholder involvement as an ongoing, iterative process [51, 52], and represents the

efforts to develop shared terminology, successful prioritisation of early and consistent engagement, and recognition of stakeholders' contributions [53].

Limitations

This intervention has subsequently been trialled [9] and found not to be effective in reducing household SHS exposure compared with usual services. However, further process evaluation and analysis of secondary outcomes [25] is planned that will explore effects on hypothesised intervention casual pathways and intervention fidelity [54].

We benefited from generous support from colleagues with deep knowledge of ayahs, social cognition models and / or the behaviour change technique taxonomy [41]. Additionally, access to the Quranic Search Tool [42] provided a starting point for engagement with faith leaders that would have been difficult to replicate without significant external support. The ease with which these resources can be replicated is not obvious but speak to the necessity to properly resource intervention development and/or adaptation activities in culturally sensitive settings [53].

This work predates a landmark series of studies [55-57] that triangulated evidence for links between social cognitive constructs and BCTs [41]. Whilst prior to the availability of the Theory and Technique Tool that resulted from these studies, it was typical as part of an intervention development process to make use of study team expertise to map social cognitive constructs identified through qualitative or quantitative inquiry to BCTs, this is a less robust method than the evidence synthesis and expert consensus approach that provided the data that is now available to support the mapping of such links. As such, the BCT mapping upon which we based our selection of ayahs may be less than optimal.

Conclusion

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501 This religious community-based intervention to reduce SHS exposure at home and improve lung
502 health among non-smokers in Bangladesh is the result of an iterative and collaborative 4-stage
503 process. It makes use of behaviour change theory to support faith-community contributions to the
504 production of culturally sensitive intervention content suitable for a mosque-based setting. Whilst
505 further process evaluation is necessary to understand its failure to affect SHS [9], this novel
506 combination of intervention development framework components demonstrates a flexible approach
507 that could provide insights for intervention development in related culturally sensitive contexts that
508 could support health behaviour change.

510 **Table 1: Initial and post-feedback ayahs, constructs, messages and coded BCTs**

Pre-feedback					Post feedback	
Week	Constructs	Ayah	Message	BCT	Ayah	Message
1 st	Attitude	Sura Al Baqara – 219 (2:219) They ask you about drinking and gambling. Say, "There is great harm in both, though there is some benefit also for the people. But the harm of the sin thereof is far greater than their benefit.	Though sometimes people think that smoking helps in some ways, the evidence that smoking and second- hand smoke cause harm in many ways is clear. Would Allah permit you something harmful? No! Tobacco is harmful, and hence it is not permissible to Allah. The sin of smoking causes you spiritual as well as physical harm.	5.1, Information about health consequences, 5.2 Salience of consequences, 5.6, Information about emotional consequences or 5.3, Information about social and environmental consequences	Surah Al-Maaida - Ayah 4 (5:4) They ask you, [O Muhammad], what has been made lawful for them. Say, "Lawful for you are [all] good foods."	[unchanged]

1	2 nd	Attitude	Sura An-Nisaa – 59 (4:59)	Allah has in His grace	9.1. Credible source	[unchanged]	[unchanged]
2			Believers! Obey Allah and	given us experts who	5.1, Information about		
3			obey the Messenger, and	he has been given	health		
4			those from among you who	authority to tell us	consequences,		
5			are invested with authority	the facts about what	5.2 Salience of		
6				heals us and what	consequences,		
7				harms us.	5.6, Information about		
8				The evidence from	emotional consequences		
9				scientists tells us that	or		
10				second-hand smoke	5.3, Information about		
11				contains more than	social and environmental		
12				7,000 chemicals.	consequences		
13				Hundreds are toxic			
14				and about 70 can			
15				cause cancer. Second-			
16				hand smoke also			
17				causes numerous			
18				health problems in			
19				infants and children.			
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36				Will you not listen to			
37				the facts? Will you			
38				not hear what your			
39				Imam says to you?			
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1	3 rd	Social	Sura Al-Ahzaab – 58 (33:58)	The evidence that	6.j. Information about	[unchanged]	The evidence that
2							
3		Norms	And those who harm	second -hand smoke	others		second-hand
4			believing men and believing	harms other is clear.	Approval		smoke harms
5			women for [something]	It can result heart	5.1, Information about		other is clear. It
6			other than what they have	attacks, stroke and	health		can result heart
7			earned have certainly born	lung cancer among	consequences, 5.2		attacks, stroke
8			upon themselves a slander	innocent adults who	Saliency of consequences,		and lung cancer
9			and manifest sin.	are exposed to it. And	5.6, Information about		among innocent
10				children exposed to	emotional consequences		adults who are
11				second-hand smoke	or 5.3,		exposed to it. And
12				are more prone to	Information about social		children exposed
13				have chest infection,	and		to second-hand
14				sneezing and	environmental		smoke are more
15				coughing. Moreover,	consequences		prone to have
16				they have a 50%			chest infection,
17				higher chance of			sneezing and
18				having ear infection.			coughing.
19				Now do you really			Moreover, they
20				want to do that to			have a 50% higher
21				your family members			chance of having
22				and your children?			ear infection. Now
23							do you really want
24				Similarly, Allah has			to do that to your
25				said – causing harm			family members
26				to others is a			and your children?
27				manifest sin.			
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1	4 th	Intention	Sura At-Takaathur – 8	These messages to	1.1. Goal setting	[unchanged]	[unchanged]
2							
3		formation	(102:8)	you are part of Allah's	(behaviour) quit attempt		
4							
5			Then, on that Day, you will	bounty to you. But	1.3. Goal setting		
6		(and	be called to account for all	you need to make a	(outcome) smoke free		
7		prompt	the bounties you enjoyed.	commitment to enjoy	home		
8		action		his bounty. This	1.4. Action planning		
9		planning)		means committing to	1.9. Commitment		
10				either quitting or			
11				smoking outside. If			
12				you are going to do			
13				this, you need to			
14				make a plan.			
15							
16				For quitting smoking			
17				at home, commit that			
18				if you reach for a			
19				cigarette – then leave			
20				the house before you			
21				light it. And for			
22				planning to quit			
23				smoking completely,			
24				commit that if you			
25				feel like smoking,			
26				then pray 2 rakat			
27				salat instantly.			
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1	5 th	Self-	Sura Ar-Ra'd – 11 (13:11)	You can trust Allah to	3.1. Social support	[unchanged]	[unchanged]
2							
3		efficacy	The fact is that Allah does	help you, but to	(unspecified)		
4							
5			not change a people's lot	receive that support,	1.4. Action planning		
6		(prompt	unless they themselves	you must take a step	1.9. Commitment		
7		Action	change their own	by yourself in faith.			
8							
9		Planning)	characteristics	Trust that Allah will			
10				give you everything			
11				you need.			
12							
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17				You can feel it			
18				difficult to quit			
19				smoking at home. But			
20				if YOU cannot make			
21				this simple change of			
22				behaviour for the			
23				sake of your family			
24				members, how can			
25				you expect Allah will			
26				help them in other			
27				ways? So, you need			
28				to make a plan that if			
29				you feel like smoking			
30				when you are at			
31				home – then leave			
32				the house before you			
33				light it.			
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1	6 th	Coping	Sura Nooh – 10-12 (71:10-	Allah knows you,	3.1. Social support	Surah Al-Maaida -	[unchanged]
2		planning	12)	Allah knows	(unspecified)	Ayah 9 (5:9)	
3			I said to them: 'Ask	everything. He knows	1.4. Action planning		
4			forgiveness from your Lord;	that you will need his	1.9. Commitment	Allah has promised	
5			surely He is Most Forgiving.	forgiveness. Be quick		those who believe and	
6			He will shower upon you	to come to Him. Trust		do righteous deeds	
7			torrents from heaven, and	that He will be with		[that] for them there	
8			will provide you with	you as you come back		is forgiveness and	
9			wealth and children, and	to the right path.		great reward.	
10			will bestow upon you				
11			gardens and rivers.	So make a plan that if			
12				you lapse, then you			
13				will call on Allah for			
14				forgiveness and			
15				recommit yourself			
16				and rehearse your			
17				plans.			
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32	7 th	Attitude	Sura Al Maaida – 90 (5:90)	Tobacco is toxic. Your	5.1. Information about	[unchanged]	[unchanged]
33			Believers! Intoxicants,	body becomes reliant	health		
34			games of chance, idolatrous	on nicotine. It doesn't	consequences,		
35			sacrifices at altars, and	relieve stress. It only	5.2 Salience of		
36			divining arrows are all	relieves withdrawal	consequences,		
37			abominations, the	syndrome from your	5.6, Information about		
38			handiwork of Satan. So turn	addiction.	emotional consequences		
39			wholly away from it that		or		
40			you may attain to true	Tobacco is the	5.3, Information about		
41			success.	handiwork of Satan.	social and environmental		
42				Do you want true	consequences		
43				success? Turn away			
44				wholly from tobacco.			
45							
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1	8 th	Attitude	Surah Al-Maaida - Ayah 100	A number of you may	9.1. Credible source	[unchanged]	[unchanged]
2							
3			(5:100)	believe that smoking	5.1, Information about		
4				is good because it	health		
5			Say, "Not equal are the evil	helps keep you warm,	consequences,		
6			and the good, although the	or stops you getting	5.2 Salience of		
7			abundance of evil might	fat, or manages your	consequences,		
8			impress you." So, fear Allah,	stress. But Allah, in	5.6, Information about		
9			O you of understanding,	his grace, has given us	emotional consequences		
10			that you may be successful.	eye to see, ears to	or		
11				hear and a mind to	5.3, Information about		
12				enquire. What do the	social and environmental		
13				experts tell us?	consequences		
14				Experts tell us that it			
15				does nothing but			
16				harm you and those			
17				who are staying			
18				beside you when you			
19				are smoking. The only			
20				relief you feel getting			
21				after smoking is the			
22				relief from			
23				withdrawal syndrome			
24				which we mistakenly			
25				think as stress relief.			
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1	9 th	Social	Sura At-Baqara – 195	Globally 6 million	6.j. Information about	[unchanged]	[unchanged]
2							
3		Norms	(2:195)	people die every year	others		
4							
5			And do good; indeed, Allah	from smoke. Those	Approval		
6			loves the doers of good.	who smoke among us	5.1, Information about		
7							
8				are directly causing	health		
9							
10				harms to others	consequences, 5.2		
11				unknowingly. So, we	Salience of consequences,		
12				need to be aware and	5.6, Information about		
13				careful about that.	emotional consequences		
14				We need to take	or 5.3,		
15				away these messages	Information about social		
16				to others. We need to	and		
17				make our families	environmental		
18				safe from this harm.	consequences		
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31	10 th	Intention	Sura Al-Baqara:269 (2:269)	Allah has given you	1.1. Goal setting	Surah Ash-Shams -	[unchanged]
32		formation	He gives wisdom to whom	wisdom, but to	(behaviour) quit attempt	Ayah 7 to 10 (91:7-10)	
33							
34			He wills, and whoever has	remember it, you	1.3. Goal setting		
35							
36			been given wisdom has	have to act on it. Only	(outcome) smoke free	And [by] the soul and	
37						He who proportioned	
38			certainly been given much	then you and others	home	it. And inspired it [with	
39			good. And none will	will be benefitted by	1.4. Action planning	discernment of] its	
40							
41			remember except those of	it.	1.9. Commitment	wickedness and its	
42			understanding.			righteousness, He has	
43				If you are going to do		succeeded who	
44				something, you need		purifies it, and he has	
45						failed who instils it	
46				to make a plan. For		[with corruption].	
47				example, if you reach			
48				for a cigarette when			
49				you are at home –			
50							
51				then leave the house			
52							
53				before you light it.			
54							
55				And for quitting			
56							
57							
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smoking, you should

plan like this - if you

feel the urge to

smoke, pray 2 rakat

salat instantly.

11 th	Self- efficacy (Prompt Action planning)	Sura At-Talaaq-4 (65:4) And whoever fears Allah - He will make for him of his matter ease.	Those who smoke can find it difficult to quit smoking or they can find it hard to go outside home every time they want to smoke. But believe it, Allah will help you if you wish to listen to him. One can make simple plans to overcome such issues. Just commit to yourself and others (if you can) that whenever you feel the urge of smoking,	3.1. Social support (unspecified) 1.4. Action planning 1.9. Commitment	Surah At-Taghaabun - [unchanged] Ayah 16 (64:16) So, fear Allah as much as you are able and listen and obey and spend [in the way of Allah]; it is better for yourselves. And whoever is protected from the stinginess of his soul - it is those who will be the successful.
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go outside home to

light it or pray 2 rakat

salat instantly.

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1	12 th	Coping	Sura Luqman – 17 (31:17)	Allah knows best	3.1. Social support	Surah Al-Hajj - Ayah 77 [unchanged]
2						
3		Planning	Son, establish Prayer, enjoin	about His creatures.	(unspecified)	(22:77)
4			all that is good and forbid	He understands that	1.4. Action planning	
5			all that is evil, and endure	we may do things	1.9. Commitment	O you who have
6			with patience whatever	that will harm us and		believed, bow and
7			affliction befalls you. *29	others. That is why,		prostrate and worship
8			Surely these have been	he encouraged us to		your Lord and do good
9			emphatically enjoined.	enjoy all that is good		- that you may
10				and forbid all that is		succeed
11				evil and keep		
12				patience in times of		
13				affliction.		
14						
15				We must remind		
16				ourselves these		
17				words of our creator		
18				again and again. We		
19				must try to make our		
20				habits safe for others.		
21				We must remember		
22				the possible harms of		
23				our behaviour to		
24				others like smoking at		
25				home and repetitively		
26				plan to keep us and		
27				our families safe from		
28				its harm.		

512

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Contributors

IK drafted the manuscript, conceived the intervention development approach, contributed to design, conduct, and interpretation of findings. ZAA contributed to design, conduct, interpretation of findings, and writing of the manuscript. CJ contributed to the intervention development approach, design, conduct, interpretation of findings, and writing of the manuscript. RH contributed to design and conduct, and interpretation of findings. NM contributed to design, conduct, interpretation of findings, and writing of the manuscript. KS conceived the intervention idea and contributed to design, conduct, interpretation of results, and writing of the manuscript. All authors participated in manuscript revisions and read and approved the final manuscript. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

690 **Declaration of interests**

691 We declare no competing interests.

692

693 **Data availability**

694 De-identified participant data will be made available from the point of, and up to 5 years after the
 695 acceptance for publication. These data can be requested from the Principal Investigator (Prof
 696 Kamran Siddiqi; kamran.siddiqi@york.ac.uk) and will be shared after the provision of a
 697 methodologically sound proposal, and only under a data-sharing agreement that provides for
 698 commitment to: using the data only for research purposes and not to identify any individual
 699 participant; securing the data using appropriate computer technology; and destroying or returning
 700 the data after analyses are completed. The proposals will be assessed and approved by members of
 701 the Programme Management Group. The intervention manual and indoor-air-quality feedback
 702 leaflet are available on the study webpage: [https://www.york.ac.uk/healthsciences/research/public-](https://www.york.ac.uk/healthsciences/research/public-health/projects/mclass11/#tab-3)
 703 [health/projects/mclass11/#tab-3](https://www.york.ac.uk/healthsciences/research/public-health/projects/mclass11/#tab-3).

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The TIDieR (Template for Intervention Description and Replication) Checklist*:

5 information

Information to include when describing an intervention and the location of the

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other [†] (details)
1.	BRIEF NAME Provide the name or a phrase that describes the intervention.	P1 Line 1	
2.	WHY Describe any rationale, theory, or goal of the elements essential to the intervention.	P5 line 109	
3.	WHAT Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	https://www.york.ac.uk/healthsciences/research/public-health/projects/mclass11/#tab-3	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities. WHO PROVIDED		Mdege et al, 2021, p 1641
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given. HOW		Mdege et al, 2021, p 1641
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or		Mdege et al, 2021, p 1641

	telephone) of the intervention and whether it was provided individually or in a group.		
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.		Mdege et al, 2021, p 1641
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.		Mdege et al, 2021, p 1641
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	n/a	
	MODIFICATIONS		
10. [‡]	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	P15 line 340-439	
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	n/a	
12. [‡]	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	n/a	

6 **** Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** –

7 use ‘?’ if information about the element is not reported/not sufficiently reported.

8 † If the information is not provided in the primary paper, give details of where this information is

9 available. This may include locations such as a published protocol or other published papers

10 (provide citation details) or a website (provide the URL).

11 ‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and
12 cannot be described until the study is complete.

13 * We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ*
14 2014;348:g1687) which contains an explanation and elaboration for each item.

15 * The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison
16 elements) of a study. Other elements and methodological features of studies are covered by other
17 reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a
18 **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT
19 statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**.
20 When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with
21 the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see [www.spirit-](http://www.spirit-statement.org)
22 [statement.org](http://www.spirit-statement.org)). For alternate study designs, TIDieR can be used in conjunction with the appropriate
23 checklist for that study design (see www.equator-network.org).

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Appendix 1: Guided checklist

Item description	Explanation	Page / Line
1. Report the context for which the intervention was developed.	Understanding the context in which an intervention was developed informs readers about the suitability and transferability of the intervention to the context in which they are considering evaluating, adapting or using the intervention. Context here can include place, organisational and wider socio-political factors that may influence the development and/or delivery of the intervention (15).	4 (101); 6 (156)
2. Report the purpose of the intervention development process.	Clearly describing the purpose of the intervention specifies what it sets out to achieve. The purpose may be informed by research priorities, for example those identified in systematic reviews, evidence gaps set out in practice guidance such as The National Institute for Health and Care Excellence or specific prioritisation exercises such as those undertaken with patients and practitioners through the James Lind Alliance.	6 (141)
3. Report the target population for the intervention development process.	The target population is the population that will potentially benefit from the intervention – this may include patients, clinicians, and/or members of the public. If the target population is clearly described then readers will be able to understand the relevance of the intervention to their own research or practice. Health inequalities, gender and	Starting 6 (141)

	ethnicity are features of the target population that may be relevant to intervention development processes.	
4. Report how any published intervention development approach contributed to the development process	<p>Many formal intervention development approaches exist and are used to guide the intervention development process (e.g. 6Squid or The Person Based Approach to Intervention Development). Where a formal intervention development approach is used, it is helpful to describe the process that was followed, including any deviations. More general approaches to intervention development also exist and have been categorised as follows (3):- Target Population-centred intervention development; evidence and theory-based intervention development; partnership intervention development; implementation-based intervention development; efficacy-based intervention development; step or phased-based intervention development; and intervention-specific intervention development. These approaches do not always have specific guidance that describe their use. Nevertheless, it is helpful to give a rich description of how any published approach was operationalised</p>	5 (115)
5. Report how evidence from different sources informed the	Intervention development is often based on published evidence and/or primary data that has been collected to inform the intervention development process. It is useful	5 (115)

intervention development process	to describe and reference all forms of evidence and data that have informed the development of the intervention because evidence bases can change rapidly, and to explain the manner in which the evidence and/or data was used. Understanding what evidence was and was not available at the time of intervention development can help readers to assess transferability to their current situation.	
Report how/if published theory informed the intervention development process	Reporting whether and how theory informed the intervention development process aids the reader's understanding of the theoretical rationale that underpins the intervention. Though not mentioned in the e-Delphi or consensus meeting, it became increasingly apparent through the development of our guidance that this theory item could relate to either existing published theory or programme theory	14 (321)
7. Report any use of components from an existing intervention in the current intervention development process.	Some interventions are developed with components that have been adopted from existing interventions. Clearly identifying components that have been adopted or adapted and acknowledging their original source helps the reader to understand and distinguish between the novel and adopted components of the new intervention.	n/a

<p>8. Report any guiding principles, people or factors that were prioritised when making decisions during the intervention development process</p>	<p>Reporting any guiding principles that governed the development of the application helps the reader to understand the authors' reasoning behind the decisions that were made. These could include the examples of particular populations who views are being considered when designing the intervention, the modality that is viewed as being most appropriate, design features considered important for the target population, or the potential for the intervention to be scaled up.</p>	<p>5 (115)</p>
<p>9. Report how stakeholders contributed to the intervention development process.</p>	<p>Potential stakeholders can include patient and community representatives, local and national policy makers, health care providers and those paying for or commissioning health care. Each of these groups may influence the intervention development process in different ways. Specifying how differing groups of stakeholders contributed to the intervention development process helps the reader to understand how stakeholders were involved and the degree of influence they had on the overall process. Further detail on how to integrate stakeholder contributions within intervention reporting are available.</p>	<p>5 (115)</p>
<p>10. Report how the intervention changed in content and format</p>	<p>Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean</p>	<p>16 (340)</p>

from the start of the intervention development process.	that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and practitioners about uncertainties relevant to their healthcare context.	
11. Report any changes to interventions required or likely to be required for subgroups.	Specifying any changes that the intervention development team perceive are required for the intervention to be delivered or tailored to specific subgroups enables readers to understand the applicability of the intervention to their target population or context. These changes could include changes to personnel delivering the intervention, to the content of the intervention, or to the mode of delivery of the intervention.	(n/a)
12. Report important uncertainties at the end of the intervention development process	Intervention development is frequently an iterative process. The conclusion of the initial phase of intervention development does not necessarily mean that all uncertainties have been addressed. It is helpful to list remaining uncertainties such as the intervention intensity, mode of delivery, materials, procedures, or type of location that the intervention is most suitable for. This can guide other researchers to potential future areas of research and	n/a

	practitioners about uncertainties relevant to their healthcare context.	
13. Follow TIDieR guidance when describing the developed intervention.	Interventions have been poorly reported for a number of years. In response to this, internationally recognized guidance has been published to support the high quality reporting of health care interventions and public health interventions. This guidance should therefore be followed when describing a developed intervention.	See attached TIDieR checklist
14. Report the intervention development process in an open access format.	Unless reports of intervention development are available people considering using an intervention cannot understand the process that was undertaken and make a judgement about its appropriateness to their context. It also limits cumulative learning about intervention development methodology and observed consequences at later evaluation, translation and implementation stages. Reporting intervention development in an open access (Gold or Green) publishing format increases the accessibility and visibility of intervention development research and makes it more likely to be read and used. Potential platforms for open access publication of intervention development include open access journal publications, freely accessible funder reports or a study	

	web-page that details the intervention development process.	
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*e.g. if item is reported elsewhere, then the location of this information can be stated here.