

1 **Title: Development and usability testing of a very brief intervention for**
2 **personalised cancer risk assessment to promote behaviour change in primary care**
3 **using normalisation process theory.**

4
5 **Running title: Development of a personalised cancer risk intervention to promote**
6 **behaviour change**

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35

36

37 **ABSTRACT**

38 Background: Cancer is the second leading cause of death worldwide. Lifestyle choices

39 play an important role in the aetiology of cancer with up to four in ten cases potentially

40 preventable. Interventions delivered by healthcare professionals (HCPs) that

41 incorporate risk information have the potential to promote behaviour change. Our

42 aim was to develop a very brief intervention incorporating cancer risk, which could be

43 implemented within primary care.

44

45 Methods: Guided by normalisation process theory (NPT), we developed a prototype

46 intervention using literature reviews, consultation with patient and public

47 representatives and pilot work with patients and HCPs. We conducted focus groups

48 and interviews with 65 HCPs involved in delivering prevention activities. Findings were

49 used to refine the intervention before 22 HCPs completed an online usability test and

50 provided further feedback via a questionnaire incorporating a modified version of the
51 NoMAD checklist.

52

53 Results: The intervention included a website where individuals could provide
54 information on lifestyle risk factors view their estimated 10-year risk of developing
55 one or more of the five most common preventable cancers and access lifestyle advice
56 incorporating behaviour change techniques. Changes incorporated from feedback
57 from the focus groups and interviews included signposting to local services and
58 websites, simplified wording and labelling of risk information. In the usability testing
59 all participants felt it would be easy to collect the risk information. 91% felt the
60 intervention would enable discussion about cancer risk and believed it had potential
61 to be easily integrated into NHS Health Checks. However, only 36% agreed it could be
62 delivered within 5 minutes.

63

64 Conclusions: With the use of NPT we developed a very brief intervention that is
65 acceptable to HCPs in primary care and could be potentially integrated into NHS
66 Health Checks. However, further work is needed to assess its feasibility and potential
67 effectiveness.

68

69

70 **Keywords:** intervention development, cancer risk, behaviour change, primary care

71

72

73 **BACKGROUND**

74

75 Cancer is now the second leading cause of death worldwide(World Health
76 Organisation, 2018). Approximately four in ten cases are thought to be preventable
77 through lifestyle change. The importance of prevention has been highlighted in both
78 the Academy of Medical Sciences “Improving the health of the public by 2040”
79 report(Sciences, 2016) and in the NHS ‘Five Year Forward View”, in which the
80 sustainability of the health system is described as being dependent on ‘radical
81 upgrade in prevention and public health’(NHS, 2014).

82

83 As described in those reports, achieving this change is likely to require interventions
84 targeted at both the population and individual level. Primary care provides an ideal
85 platform from which to deliver individual-level interventions. Not only does primary
86 care provide over 300 million patient consultations each year in England alone(NHS,
87 2014), but it is also the site in which many other prevention programmes, including
88 the NHS Health Check and Diabetes Prevention programmes in England(*NHS
89 Diabetes Prevention Programme*, no date; Public Health England, 2014), are already
90 delivered.

91

92 A common component of many prevention programmes is the estimation and
93 communication of risk of disease. The evidence for behaviour change following
94 provision of risk information in general is limited(Usher-Smith *et al.*, 2015; Hollands
95 *et al.*, 2016; French *et al.*, 2017). However, a recent systematic review of
96 randomised trials showed that interventions incorporating personalised non-genetic
97 cancer risk information were associated with increased odds of remaining a former

98 smoker in those who had recently quit smoking and increased sun protection habits,
99 skin self-examination and breast examination(Juliet A Usher-Smith *et al.*, 2018).
100 Behaviour change interventions incorporated within breast and colorectal cancer
101 screening programmes have also achieved significant reductions in multiple risk
102 factors(Emmons *et al.*, 2005; Anderson, Craigie, *et al.*, 2014; Anderson, Macleod, *et*
103 *al.*, 2014). Provision of cancer-specific risk information alongside lifestyle advice at
104 an individual level within the context of primary care may therefore support
105 population level interventions to promote behaviour change.

106

107 As with all healthcare professional led interventions, success depends on the
108 engagement of those delivering the intervention. While studies have confirmed that
109 healthcare professionals in primary care consider prevention an important part of
110 their role, delivering prevention activities is considered difficult for many and is not
111 routinely conducted(Brotons *et al.*, 2005; Noordman, Verhaak and van Dulmen,
112 2010; McIlpatrick *et al.*, 2013; Usher-smith *et al.*, 2017). Barriers identified include
113 lack of time(Brotons *et al.*, 2005; McIlpatrick *et al.*, 2013; Usher-smith *et al.*, 2017),
114 training(McIlpatrick *et al.*, 2014; Usher-smith *et al.*, 2017) and availability of clear
115 resources for patients(Usher-smith *et al.*, 2017). To address these barriers and other
116 factors contributing to the ‘implementation gap’ between research and
117 practice(Olswang and Prelock, 2015), a number of theories have been developed.
118 One is normalisation process theory (NPT), which provides a framework for
119 understanding how and whether complex interventions become routinely
120 embedded in health care practice(May *et al.*, 2009). It focuses on the work that
121 individuals and groups do to enable an intervention to become normalised and

122 includes four components: coherence (sense-making), cognitive participation
123 (engagement), collective action (enactment), and reflective monitoring (appraisal). It
124 has been widely used to successfully retrospectively analyse the implementation of
125 interventions(McEvoy *et al.*, 2014; May *et al.*, 2018) and has also been proposed as a
126 tool to be applied prospectively to raise awareness about facilitators and barriers to
127 successful implementation(Murray *et al.*, 2010). Used in this way it can act as a
128 'sensitising tool'(Murray *et al.*, 2010) to encourage thinking through issues around
129 implementation when designing interventions.

130

131 The MRC guidance for development and evaluation of complex interventions(Craig
132 *et al.*, 2008) and NICE Public Health guidance for behaviour change
133 interventions(National Institute for Health and Care Excellence., no date) also
134 emphasize the importance of the early phases of intervention development and the
135 need to ensure that interventions build on the skills, talents and capacity of
136 healthcare professionals and are consistent with other local and national
137 interventions and programmes(National Institute for Health and Care Excellence., no
138 date).

139

140 We aimed to use NPT alongside healthcare professionals currently working within
141 primary care to guide the development of a very brief risk-based intervention that
142 could be used within primary care to support patients to make lifestyle changes to
143 prevent cancer.

144

145 **METHODS**

146

147 The overall process for developing and testing the intervention is summarised in
148 Figure 1.

149 **Figure 1: Development and testing process of the prototype intervention**
150

151 **Stage 1: Development of a prototype intervention**

152

153 To guide the initial format of the prototype and how it might fit within the primary
154 care context we began by considering the four components within each of the core
155 constructs within normalisation process theory: coherence; cognitive participation;
156 collective action; and reflexive monitoring. Coherence refers to the sense-making by
157 participants either individually or collectively when faced with the implementation of
158 a new set of practices; cognitive participation relates to participant understanding
159 and engagement with the new set of practices within their current roles; collective
160 action considers the capacity and support needed for the incorporation of the new
161 practices into existing procedures; and reflexive monitoring describes participant
162 appraisal, evaluation and monitoring of the impact of the new practices on
163 themselves and their working roles(*Normalisation process theory constructs*, no
164 date). Guided by the questions within the NPT toolkit(*Normalisation process theory-*
165 *NPT toolkit*, no date) we considered the application of each of these constructs to
166 the intervention in turn.

167

168 To be consistent with the overall structure of other local and national risk
169 communication based interventions currently in use in primary care, such as NHS

170 Health Checks(Public Health England, 2016), we considered the intervention in three
171 parts:

172

173 i) Risk assessment- a risk assessment tool to enable collection of diet and
174 other lifestyle risk factors for cancer, either independently or with a
175 healthcare professional.

176

177 ii) Risk communication- a web-based tool to display the estimated risk of
178 developing one or more cancers based on potentially modifiable lifestyle
179 risk factors.

180

181 iii) Risk management advice- the opportunity to discuss behaviour change
182 using evidence-based information on diet and lifestyle risk factors and
183 signposting to existing services.

184

185 ***i) Development of risk assessment***

186 To facilitate implementation, we chose to develop an online lifestyle based risk
187 assessment with an integrated data collection tool that required only simple data on
188 lifestyle factors that could be collected by healthcare professionals in a few minutes
189 or self-completed by patients either in the waiting room or online prior to their
190 appointment. To enable individuals to see the effect of lifestyle on multiple cancers,
191 we chose to estimate the 10-year risk of developing one of the five commonest
192 preventable cancers among men and women in the UK. These are lung, colorectal,

193 bladder, kidney and oesophageal cancer for men; and breast, lung, colorectal,
194 endometrial and kidney cancer for women.
195
196 The development and assessment of the performance of these lifestyle based risk
197 assessments is discussed in detail in a separate paper(Juliet A. Usher-Smith *et al.*,
198 2018). In summary, established lifestyle risk factors from the European Code against
199 Cancer(Leitzmann, Boutron-Ruault, *et al.*, 2015; Leitzmann, Powers, *et al.*, 2015;
200 Leon M, Peruga A, McNeill A, Kralikova E, Guha N, Minozzi S, 2015; Norat *et al.*,
201 2015; Scoccianti *et al.*, 2015) and estimates of relative risks from meta-analyses of
202 observational studies were used to calculate an individuals' risks of developing one
203 or more of the five cancers relative to a recommended lifestyle. Mean values for risk
204 factors from the Health Survey for England (HSE) 2005 (available from:
205 [https://digital.nhs.uk/data-and-information/publications/statistical/health-survey-](https://digital.nhs.uk/data-and-information/publications/statistical/health-survey-for-england)
206 [for-england](https://digital.nhs.uk/data-and-information/publications/statistical/health-survey-for-england)) and the National Diet and Nutrition survey (NDNS) years 1-4 (2008/12)
207 (available from: <https://discover.ukdataservice.ac.uk/catalogue/?sn=6533>)and mean
208 10-year estimated absolute risks from routinely available sources (Statistics, 2015a,
209 2015b) were then used to calculate the estimated absolute risk of developing one or
210 more of the cancers over a 10-year period. The performance of the risk assessment
211 was then validated using data from 23,768 participants (12,828 women and 10,940
212 men) in the EPIC-Norfolk cohort(N Day, S Oakes, R Luben, KT Khaw, S Bingham, A
213 Welch, 1999) who had at least 10-year follow-up and data for all risk factors and no
214 previous history of diagnosis or any of the chosen cancers at baseline.

215

216 ***ii) Development of risk communication***

217 To enable communication of the risk to participants we developed a web-based tool
218 integrated within the Gorilla.sc research platform (www.gorilla.sc/about). In order to
219 choose the format(s) in which to present the risk we conducted several steps. This
220 included: looking back at pilot work with members of the public in which they had
221 been presented with their risk of individual cancers in four different ways and focus
222 groups with healthcare professionals within primary care which have been reported
223 separately(Usher-smith *et al.*, 2017; Usher-Smith *et al.*, 2017); a scoping review of
224 literature published up to February 2017 that reported on the effectiveness and
225 patient preferences of different risk presentation formats used in cardiovascular
226 disease and cancer(Fortin *et al.*, 2001; Julian-Reynier *et al.*, 2003; Kirby and Machen,
227 2009; Sheridan *et al.*, 2009; Hill *et al.*, 2010; Waldron *et al.*, 2011; Dorval *et al.*, 2013)
228 ; reference to best practice guidance for communication of risk(Lipkus, 2007;
229 Trevena *et al.*, 2013; Zipkin *et al.*, 2014); and discussions with patient and public
230 representatives and experts in the field.

231

232 ***iii) Development of risk management advice***

233 Given the known challenges to achieving behaviour change and the evidence from
234 systematic reviews of the limitations of risk provision alone(Brindle *et al.*, 2006;
235 Usher-Smith *et al.*, 2015; French *et al.*, 2017), we set out to incorporate established
236 behaviour change techniques (BCTs) into the intervention, within the consultation
237 with the healthcare professional, on the website and as a leaflet to be given to
238 patients after the consultation. We began with the BCTs within the BCT Taxonomy
239 (v1)(Michie *et al.*, 2013) which were judged appropriate by a consensus of experts in
240 behaviour change and most frequently used for enablement and education

241 interventions(Michie, Atkins and West, 2014). From that list we then used the
242 following three criteria to select which to include in the intervention:

243

- 244 1. Evidence for effectiveness of BCTs in this context
- 245 2. Relevance to the context i.e. BCTs that could be used within face-to-face
246 interventions within primary care to promote lifestyle change to reduce
247 future risk of cancer
- 248 3. Feasibility i.e. can be delivered by nurses/Health care assistants within 5
249 minutes in primary care

250

251 To identify evidence for the first of these criteria, we performed a scoping review of
252 the literature. This included searching online bibliographic databases in May 2017 to
253 identify systematic reviews and meta-analyses published in English and reporting the
254 effectiveness of the inclusion of individual BCTs on behaviour change. We then also
255 screened the reference lists of identified papers for other relevant reviews.

256

257 **Stage 2: Refinement and testing of prototype intervention**

258

259 ***Focus groups and interviews with healthcare professionals***

260 To enable us to demonstrate the prototype intervention and receive direct feedback
261 from key stakeholders, we conducted focus groups and face-to-face interviews with
262 healthcare professionals involved in delivering preventive healthcare across the East
263 of England and London between June-August 2017. Approvals were obtained from

264 the University of Cambridge Psychology ethics committee (Ref: PRE.2017.043) and
265 the Health Research Authority (HRA) (Ref: 17/HRA/1948).

266

267 *Participants and recruitment*

268 To recruit healthcare professionals currently working within general practice, letters
269 of invitation and the study information leaflet were emailed to all GPs, practice
270 nurses and healthcare assistants across Cambridge and Peterborough by the local
271 Clinical Lead for the NHS Health Check programme. Those interested in taking part
272 were invited to contact the research team directly. Healthcare professionals working
273 within three health service commissioned providers of lifestyle advice were similarly
274 emailed a letter of invitation along with the study information leaflet by their
275 manager and invited to attend one of several planned focus groups. The local NIHR
276 Clinical Research Network also provided assistance in the recruitment of healthcare
277 professionals from local general practices.

278

279

280 *Data collection*

281 All focus groups and interviews were held at the participants' place of work and
282 were led by a non-clinical researcher experienced in qualitative research (KM). Each
283 lasted between 20 and 60 minutes. Written consent was obtained from all
284 participants. Each focus group began with a presentation showing screen shots of
285 the questions used to collect the risk factor information, presentation of risk and
286 web-based lifestyle advice. Copies of the behaviour change leaflet were then handed
287 out for participants to read. The discussions that followed were informed by a topic

288 schedule (Appendix 1) which incorporated the first three NPT constructs (coherence,
289 cognitive participation and collective action). We chose not to include the fourth
290 construct, reflexive monitoring, as this relates to how individuals and groups assess
291 how the intervention affects them in practice, and we felt that this would be difficult
292 for participants at this stage to consider. Within focus groups we also explored
293 views of the participants on the overall format, content and length of the prototype
294 intervention, as well as any barriers and facilitators to its incorporation into practice.

295

296 *Analysis*

297 The focus groups and interviews were audio-recorded and then transcribed verbatim
298 and analysed using an iterative process which started near the beginning of data
299 collection. Throughout this process the qualitative data was fine-coded by one
300 researcher (KM) with the aid of NVivo software (QSR International, version 11).
301 Emergent themes were identified using thematic analysis(Braun and Clarke, 2006)
302 and then discussed among the wider research team and used to refine the prototype
303 intervention.

304

305 ***Usability testing and feedback from healthcare professionals***

306 After further refinement of the intervention based on the findings from the focus
307 groups and interviews, we developed the web-based intervention and invited
308 healthcare professionals to trial the website and provide feedback on its usability
309 and the intervention as a whole.

310

311 *Participants and recruitment*

312 All participants who had taken part in a focus group or interview and who had
313 provided a valid email address were sent an email with a link to the intervention
314 website. A unique study ID was included in each email that enabled the participants
315 to log in and work through the entire intervention as if they were delivering it in
316 practice. This included collection of information about lifestyle risk factors,
317 presentation of the estimated risk, setting target values and seeing the impact of
318 those changes on the estimated risk, and then viewing all the pages of the behaviour
319 change leaflet. They were then automatically directed to an electronic
320 questionnaire.

321

322 *Data collection*

323 The electronic questionnaire was in two parts, Appendix 2. The first asked
324 participants about the usability of the website and the clarity of the information
325 provided. The second focused on the potential for the intervention to be
326 incorporated into practice with questions covering the first three components of
327 NPT adapted from the NoMAD checklist(Finch *et al.*, 2013) in line with guidance from
328 the NPT website (*Normalisation process theory*, no date). In the second section we
329 also included specific questions about the anticipated duration of the intervention
330 and the potential for it to be incorporated within NHS Health Checks, routine
331 consultations, chronic disease reviews and lifestyle advice consultations.

332

333 *Analysis*

334 Data from the questionnaire were analysed descriptively and are presented as
335 frequencies and means (\pm standard deviation, SD). Agreement with statements from

336 the NoMAD checklist was converted into a 5-point scale ranging from 1 (Strongly
337 disagree) to 5 (Strongly agree). Those selecting the option 'Not applicable to my role'
338 were treated as missing data for that question.

339

340 **RESULTS**

341

342 **Stage 1: Development of a prototype intervention**

343

344 Table 1 shows how each of the four components of the four core constructs within
345 normalisation process theory were used to inform decisions about the overall
346 concept, content and delivery of the intervention. Particular considerations
347 included making the intervention simple to describe to patients; ensuring intuitive
348 navigation to minimise training requirements; and designing it to fit within current
349 prevention activities within primary care such as NHS Health Checks.

350

351 ***Insert Table 1 here***

352

353

354 ***ii) Development of risk communication***

355 Table 2 details the key findings which we considered when choosing the format in
356 which to communicate the risk. In addition to the previously published pilot work
357 (Usher-Smith *et al.*, 2017) and best practice guidance (Fortin *et al.*, 2001; Lipkus,
358 2007; Waldron *et al.*, 2011), we identified seven studies [13–18]. Key considerations
359 included: the appropriate use of a colour scale to demonstrate the level of risk;

360 inclusion of relative risk to promote behaviour change; a 10-year risk estimate to
361 align with current cardiovascular disease risk estimates; and the ability to change
362 modifiable risk factors and view their effect on overall risk estimate. The chosen
363 format for risk presentation was a bar graph displaying a 10-year risk estimate. This
364 included colour shading to communicate the level of risk on a scale from green to
365 red. The graph axis described an individual's risk level as the number of times higher
366 than that of a person following all of the recommended lifestyle guidance. The risk
367 presentation displays this as an additional bar for reference. To aid interpretation,
368 the percentage value of the risk level can also be viewed. On setting new target
369 values for lifestyle changes, the bar graphs displays an additional level of risk to
370 visualise the consequent potential risk reduction. On completion, the bar graph
371 communicates three levels of risk: 1) current, 2) potential future risk after making
372 lifestyle improvements and 3) the risk if following all of the recommended lifestyle
373 guidance.

374

375 ***Insert Table 2 here***

376

377

378 ***iii) Development of risk management advice***

379 From the 93 BCTs within the BCT Taxonomy (v1)(Michie *et al.*, 2013), 58 were judged
380 appropriate by a consensus of experts in behaviour change and most frequently used
381 for enablement and education interventions(Michie, Atkins and West, 2014). We
382 then identified four systematic reviews(Michie *et al.*, 2009; Lara *et al.*, 2014;
383 McDermott *et al.*, 2016; Samdal *et al.*, 2017) addressing which of these BCTs are

384 most effective in the context of changes in physical activity and diet. To our
385 knowledge, no systematic reviews have reported the effectiveness of BCTs in the
386 context of alcohol consumption and smoking. Overall, the evidence for effectiveness
387 of the BCTs was mixed. However, the reviews did identify a number of BCTs
388 associated with intention and behaviour change. In the study by Lara *et al*, 2014, the
389 BCTs “plan for social support” and “goal setting (outcome)” were reported to make
390 clinically important improvements in fruit and vegetable consumption(Lara *et al.*,
391 2014). McDermott *et al*, 2016 reported that no BCTs were associated with
392 significant positive effects on behaviour. However, they did identify that there was a
393 significant positive association of intention with the BCT “provide information on the
394 consequences of behaviour in general”(McDermott *et al.*, 2016). Michie *et al*, 2009
395 reported that interventions designed to promote physical activity and healthy eating
396 appear to be more effective if the BCT “self- monitoring” and at least one of the four
397 other self-regulatory techniques derived from control theory(Carver and Scheier,
398 1982) (“prompt intention formation”, “prompt specific goal setting”, “provide
399 feedback on performance”, “prompt review of behavioural goals”) were
400 included(Michie *et al.*, 2009). Similarly, a more recent study by Samdal *et al*, 2017
401 described “self-monitoring of behaviour” and “goal setting of behaviour” as
402 associated with a positive intention effect for both short and long-term
403 changes(Samdal *et al.*, 2017).

404

405 The reviews also identified BCTs negatively associated with change. For example,
406 “exploring the pros and cons of behaviour change” was reported as negatively
407 associated with changes in diet and physical activity in overweight and obese adults

408 (Samdal *et al.*, 2017), “relapse prevention/coping planning” was associated with a
409 negative change in intention(McDermott *et al.*, 2016), and “provide feedback on
410 performance” was reported to have a significant negative effect on
411 behaviour(McDermott *et al.*, 2016). We, therefore, excluded these BCTs from our
412 selection.

413

414 After assessing each of the remaining BCTs against our additional criteria of
415 relevance to the context of primary care and practicability to deliver within a five
416 minute consultation, we selected 13 to include in the intervention (Table 3). These
417 include social support (unspecified); goal setting (behaviour); goal setting (outcome);
418 and self-monitoring of behaviour and, as described in Table 3, are incorporated
419 within both the consultation itself and the written information provided as part of
420 the intervention. For example, the website allows demonstration of the estimated
421 cancer risk and impact of lifestyle change, and the behaviour change leaflet
422 (appendix 3) includes generic advice on goal setting and support with signposting to
423 local services and information on each of the lifestyle risk factors with details on
424 their association with cancer, suggestions for lifestyle improvements and space to
425 write goals. The prototype intervention therefore consisted of a website where on
426 completion of a questionnaire on lifestyle cancer risk factors, a 10-year risk estimate
427 is presented as a coloured graded bar graph. Lifestyle improvements discussed
428 supported by weblinks and paper copy of a behaviour change leaflet including
429 signposting to local services, target values set for lifestyle risk factors entered onto
430 the website and a target level of risk calculated to visualise potential risk reduction.

431

432 ***Insert Table 3 here***

433

434 **Stage 2: Refinement and testing of prototype intervention**

435

436 ***Focus groups and interviews with healthcare professionals***

437 Sixty-five healthcare professionals who deliver prevention services within primary
438 care took part across nine focus groups and two interviews to provide feedback on the
439 prototype intervention. The characteristics of participants are shown in Table 4.
440 Participants included general practitioners, practice nurses, healthcare assistants,
441 health trainers and managers. Forty-one provided services working for a lifestyle
442 provider and 24 in general practice. The sample included 14 men and 51 women, with
443 varying years of experience in their current working roles. The index of multiple
444 deprivation (IMD) scores for each of the six general practices were collected (median
445 12.3, range 9-20.3), five of which were in the highest quintile in the distribution for
446 England. Each of the practices reported that at least 80% (range 79.9-90.7%) of their
447 patient population were of White ethnic origin, followed by at least 6% from Asian
448 ethnic origin (range 6-13.9%). A small proportion were from other ethnic groups,
449 Black (range 1-2.3%), Mixed (range 1.6-3.5%) and other Non-White (range 0-1.7%).

450

451

452 ***Insert Table 4 here***

453

454

455

456 Overall participants were enthusiastic and supportive about the intervention and felt
457 that it showed promise for use within primary care consultations and potential to
458 benefit patients and the NHS system as a whole.

459

460 *"I think it would help motivate people and actually help them see the bigger picture but also*

461 *help them take ownership themselves and have that motivation, and seeing where it all*

462 *connects and what they can do themselves with the right education and support and help."*

463 *Focus group 3, Lifestyle provider*

464

465 *"I would have thought so because obviously anybody that we can prevent or lower their risk*

466 *of is less work for us and less work for secondary care and less cost to the NHS, and at very*

467 *little cost to ourselves."* Focus group 9, General practice

468

469 We have reported below in turn the results within each of the three constructs of

470 NPT incorporated into the focus group discussions: coherence; cognitive

471 participation; and collective action.

472

473

474 *Coherence*

475 Within the construct of *coherence*, which is defined as sense making, there were

476 several components discussed by participants in each of the focus

477 groups/interviews. All participants could see the importance and benefits of the

478 intervention and the potential value it could have within primary care consultations,

479 especially within the current prevention activities they perform as part of their role.

480 Particular reference was made to the intervention's potential to act as an additional

481 motivator to behaviour change within other existing conversations about disease risk

482 including cardiovascular disease.

483

484 *"If someone has got high cardiovascular risk and they've got a high cancer risk as well...I*
485 *think if they get all the information in one lump sum they're more prone to be open to the*
486 *suggestion of change."* Focus group 1, Lifestyle provider

487

488 *"I suppose it's an additional motivator to reinforce the lifestyle message that you're trying to*
489 *give, because you're not giving them any different advice, you're still saying, do all the same*
490 *things in terms of diet and lifestyle."* Focus group 5, General Practice

491

492 Many participants were also able to build on their shared experiences of delivered
493 risk information and show understanding of the aims and objectives of the
494 intervention. Visualisation of the change in risk level after a discussion on goal
495 setting for behaviour change was particularly recognised as of value.

496

497 *"Definitely think seeing that change, so looking at the risk now, then actually how it can*
498 *almost be halved if it was going with like the target values that it's easier for them to*
499 *visualise that, rather than just being told, "Ah it could reduce".* Focus group 4, Lifestyle
500 *provider*

501

502 *"I think something interactive is always helpful than just kind of giving information, so*
503 *something like goal setting...that can definitely help"* Focus group 2, Lifestyle provider

504

505 This extended to consideration of its delivery, which included the content required
506 to discuss effectively the risk assessment and lifestyle advice with patients.

507

508 *“If we only delivered the figure (risk score) to the client, it still remains very abstract to them,*
509 *so what we need to focus the discussion on is exactly what’s going on and what’s*
510 *participating to that risk and how we can work with it” Focus group 4, Lifestyle provider.*

511

512 *Cognitive participation*

513 As part of the discussion, themes related to *cognitive participation*, defined broadly
514 as engagement, were considered. Discussion around this focused on the delivery and
515 incorporation of the intervention. Most participants reported how the delivery of the
516 intervention had the potential to be part of their existing role, and suggested specific
517 procedures that would enable implementation.

518

519 *“If a template (electronic) was designed for this then that would be a reminder to us to*
520 *discuss it. And for the patient it would mean that a lot more information is given and advised*
521 *and they can take action on their lifestyle and make them aware of it” Focus group 10,*

522 *General Practice*

523

524 To ensure that the intervention had the potential to fit within existing practice,
525 discussion also focused on how healthcare professionals could work together to
526 incorporate ways of delivery. Many participants showed willingness to be involved
527 in the delivery of the intervention as part of their role and could see how this could
528 extend to other members of the healthcare team. Most participants recruited from
529 general practice agreed that, after training, practice nurses or healthcare assistants,
530 could deliver the intervention.

531

532 *“I think if some training is given I’m sure they’d (Healthcare assistants) be fine, and with our*

533 *support, nurses' support, I'm sure they would be able to do that." Focus group 10, General*
534 *Practice.*

535

536 *Collective Action*

537 Participants discussed several aspects of *collective action*, defined as support for
538 delivery, with specific emphasis on the operationalisation of the intervention. Many
539 described availability of resources and integration into existing work within primary
540 care as of importance to its effectiveness.

541

542 Within the discussions around resources, most participants agreed that having time
543 available within the consultation was essential to the success of intervention
544 delivery. This included time to explain the risk presentation, discuss lifestyle
545 changes, offer support, and answer questions. The time required for completion
546 was felt to be dependent on the individual patients' personality and level of risk.

547

548 *"It depends on the patient. Some people may get really anxious and spend another 10*
549 *minutes discussing that, and others will be less anxious and go home. It's hard to predict. "*

550 *Focus group 5, General Practice*

551

552 Alongside time availability, sufficient practitioner training and practical resources
553 were considered by some participants to be important to patient understanding and
554 acceptance of the risk and lifestyle information.

555

556 *"We need to have the sufficient training to do that because I know it's all very well that we*
557 *sit and we give the information but for them (patients) to fully understand the risks, we need*

558 *proper training and showing they can reduce the risk but also how we put it across to them.*

559 *Because it's got to be a very diplomatic, calm way for them to understand and process the*

560 *information" Focus group 2, Lifestyle provider*

561

562 *"Practical problems that we don't have colour printers and that is very much geared towards*

563 *the colour." Focus group 7, General practice*

564

565 During discussion, many participants went further and evaluated the potential

566 integration of the intervention into their existing work. NHS Health Checks were

567 highlighted as an ideal opportunity for integration as conversations of disease

568 prevention and lifestyle behaviour change are already taking place with patients.

569

570 *"If it's associated with NHS health checks you already get a BMI, the smoking, alcohol and*

571 *the physical activity as well. And as part of the diet I ask them and normally I type up what*

572 *they say about diet, if they're having their five a day (fruit and vegetables) or not at all, and*

573 *the same with the alcohol. So it's quite simple and it's all the questions you're already asking*

574 *for the NHS health checks" Focus group 10, General practice*

575

576 One participant also felt that integration into NHS Health Checks would be received

577 favourably by patients, as many wish to receive comprehensive healthcare from

578 their general practice at each consultation.

579

580 *"I think that would be great actually...some patients expect more when they come for their*

581 *health checks, especially like between 40s and 60s when they work and they find it difficult to*

582 *come for an appointment, they want everything squeezed in that appointment and they*

583 *would really want to talk more, not just the blood pressure and weight.” Focus group 10,*

584 *General Practice*

585

586 However, this was not a universal view with another participant wondering if

587 inclusion into NHS health checks would be too much information for the patient to

588 receive in one consultation.

589

590 *“I think we just need to be mindful that it may be a little bit heavy for the patient to handle all*

591 *(CVD, cancer, diabetes, dementia) in one conversation perhaps.” Focus group 4, Lifestyle*

592 *provider*

593

594

595 *Key feedback and suggestions for improvement*

596 Participants also provided specific feedback and suggestions to improve the

597 intervention. Changes made in response to this included: amendment of the risk

598 presentation to simplify the wording; the option to display risk percentages to

599 enhance interpretation; provision for participants to return to the website to view

600 the risk score and behaviour change advice at a later date; portion sizes chart

601 available to help collection of risk factor information; and inclusion of additional

602 information for signposting to local services and websites. Suggestions that we

603 chose not to incorporate included the possibility to view the risk factor information

604 of the average person rather than the recommended lifestyle guidance, text

605 message reminders of the goals set during the intervention delivery, and the option

606 to print in colour. After consideration, it was felt that including additional

607 information about the average person alongside a person of their same age and sex

608 with the recommended lifestyle could be potentially confusing and that adding text
609 message reminders would substantially complicate the delivery, and therefore
610 implementation. It was also not feasible to provide colour printing in practices.

611

612 ***Usability testing and feedback from healthcare professionals***

613 Sixty out of the 66 focus group/interview participants agreed to be contacted for
614 participation in the usability testing. Of the 60 invited, 57 provided valid email
615 addresses. 22 of those completed the usability testing and feedback questionnaire
616 (Table 4).

617

618 Over 95% felt that collecting the risk factor information and using the website was
619 very easy or easy and that the risk presentation and lifestyle information were very
620 clear or clear. 95% also stated that they could use the website in its current form
621 with only seven of the 22 participants indicating that they would probably or
622 definitely need training. Of those seven, five preferred face-to-face training with a
623 member of the study team, one an online module and one a step-by-step written
624 guide. However, 27% of participants responded that they were unaware of the
625 option of set targets and 5% that they had been unable to set targets.

626

627 Overall, participants felt the intervention had the potential to become a normal part
628 of their work (mean score 8.0 (SD 1.5, n=21) on a scale from 1 (not at all) to 10
629 (completely)). Figure 2 shows a summary of the mean responses to individual
630 questions addressing coherence, cognitive participation and collective action. The
631 highest scores reported (mean score 4.45 (SD 0.49), n=21) on a scale from 1 (strongly

632 disagree) to 5 (strongly agree)) indicated participants agreed/strongly agreed that
633 they could see the potential value of the intervention and more specifically its use in
634 the primary care setting (mean score 4.33 (SD 0.89), n=20). In contrast, lower scores
635 were reported by participants when on considering if the intervention differed from
636 usual ways of working (mean score 3.63 (SD 0.56), n=22). Confidence in others to
637 deliver the intervention (mean score 3.90 (SD 0.41), n=22) and belief that the
638 intervention could easily integrate into existing work (mean score 3.94 (SD 0.75), n=
639 19) were also reported with moderate agreement by participants.

640

641 When asked specifically whether they believed the intervention could easily be
642 integrated into practice, over 90% (n=21) of respondents strongly agreed or agreed
643 that it could easily integrate into NHS Health Checks, chronic disease reviews or
644 lifestyle advice sessions. Fewer (74%, n=19), however, strongly agreed or agreed that
645 it could easily integrate into routine practice, with five (26%, n=19) neither agreeing
646 nor disagreeing. Consistent with the lower scores in the collective action domains
647 regarding sufficient resources (mean score 3.52 (SD 0.58)) and potential for
648 management to adequately support the delivery of the intervention (mean score
649 3.57 (SD 0.59)), only eight (38%, n=21) agreed that the intervention could be
650 delivered within five minutes, with five (24%, n=21) neither agreeing nor disagreeing
651 and eight (38%, n=21) either disagreeing or strongly disagreeing.

652

653 **Figure 2: Usability testing results**

654

655 *Key feedback and suggestions for improvements*

656 In response to the difficulties some healthcare professionals had setting targets we
657 changed the layout and some of the text on the website to make this step clearer.
658 Participants also provided further suggestions for refinement of the intervention in
659 the free text questions following the usability testing. These included changes to the
660 units of measurement for calculation of alcohol consumption and body mass index
661 and the option to print individual pages of the lifestyle leaflet to support specific
662 goals.

663 In response to the feedback gathered from the healthcare professionals on aspects
664 of training, we also devised a face-to-face training package, which could be delivered
665 by the study team and included the opportunity to simulate delivery of the
666 intervention on the website to gain familiarity.

667

668 **DISCUSSION**

669

670 **Key findings**

671 In this paper we have described the development of a very brief intervention to
672 deliver personalised cancer risk information in primary care and demonstrated the
673 value of integrating theory- and evidence-based approaches with primary data
674 collection in that process. By using the NPT framework prospectively to guide the
675 overall format of the intervention and behaviour change theory and published
676 literature to guide the content, we were able to systematically identify key
677 implementation considerations at the design stage and select risk presentation
678 formats and behaviour change techniques associated with changes in the target
679 behaviours, increasing the potential both for future incorporation of the intervention

680 into practice and intervention effectiveness(Baker *et al.*, 2010; Glanz and Bishop,
681 2010). Including qualitative data collection with healthcare professionals involved in
682 delivering prevention activities within primary care throughout the process further
683 allowed us to rehearse the prototype intervention with those who will be delivering
684 it and refine the intervention in response to their comments. Feedback on the initial
685 prototype suggested support and enthusiasm for its use, highlighting its potential
686 benefit to patients, especially acting as an additional motivator to behaviour change
687 within other current conversations of risk in primary care, namely in NHS Health
688 Checks. Feedback on the intervention and the results of usability testing indicated
689 that healthcare professionals found the intervention to be acceptable, understood
690 its purpose, and believed that it had the potential for implementation into primary
691 care consultations. They could also see the potential value of the intervention and its
692 ability to promote lifestyle changes. However, they remained concerned about
693 whether sufficient time, resources and support would be available.

694

695 A particular strength and novel aspect of our approach is the use of NPT
696 prospectively as a framework when considering the overall format of the
697 intervention. In a recent systematic review of the use of NPT in feasibility studies and
698 process evaluations(May *et al.*, 2018), only one published study has used NPT
699 prospectively in the intervention development phase of a study(Brooks *et al.*, 2015).
700 We chose NPT because it focuses on understanding how and whether complex
701 interventions become routinely embedded in health care practice(May *et al.*, 2009).
702 This includes components relevant to both the individual and the context in which
703 the intervention will be delivered. This was important as we had identified from

704 previous research with healthcare professionals that the main barriers to discussing
705 cancer risk in practice included individual concerns about understanding and
706 communicating risk and context specific needs for time and resources(May *et al.*,
707 2009). While there are other approaches we could have applied, such as
708 intervention mapping(Bartholomew, Parcel and Kok, 1998) and the consolidation
709 framework for implementation research (CFIR) (Damschroder *et al.*, 2009), the
710 accompanying NoMAD checklist also provided key questions through which we could
711 obtain feedback from healthcare professionals across the first three domains of NPT.

712

713 This feedback was important. At a time when both workload is increasing and
714 funding is decreasing, the engagement of those working within primary care is more
715 important than ever. Complexity science has also shown that in complex adaptive
716 systems, such as healthcare(Braithwaite *et al.*, 2018), professionals tend to accept
717 new ideas based on their own logic rather than the views of others, and are more
718 likely to accept change when they are involved in the process than when change is
719 imposed on them by others(Braithwaite, 2018). Engaging with healthcare
720 professionals at an early stage in the intervention development process therefore
721 allowed us to incorporate the views of professionals who would ultimately deliver
722 the intervention and maximise the likelihood of future incorporation in practice.

723 Consistent with the concept of intervention plasticity within NPT, and analogous to
724 the distinction between the 'core components' and the 'adaptable periphery'
725 described with the Consolidated Framework For Implementation Research
726 (CFIR)(Damschroder *et al.*, 2009), we also did not attempt to develop a standardised
727 process for the delivery of the intervention. Instead we consider the intervention as

728 a set of tools which healthcare professionals can adapt to different consultations and
729 patient groups. For example, in an NHS Health Check the healthcare professionals
730 may choose to complete the risk assessment and risk communication elements
731 alongside the assessment and communication of CVD risk and then discuss the risk
732 management advice for both cancer and CVD together, or may choose to separate
733 discussions about CVD and cancer within the consultation.

734

735 The overall enthusiasm we found amongst these healthcare professionals for the
736 intervention mirrors that seen in other studies which have found that primary care
737 healthcare professionals consider prevention activities an important aspect of their
738 role (Brotons *et al.*, 2005; McIlfatrick *et al.*, 2013, 2014; Usher-smith *et al.*, 2017). As
739 in this study, many also believed patients wanted to change and would follow their
740 recommendations, although belief was higher amongst practice nurses (McIlfatrick *et*
741 *al.*, 2014) than GPs (McIlfatrick *et al.*, 2013). The concerns about time and resources
742 are also consistent with previous research (Brotons *et al.*, 2005; McIlfatrick *et al.*,
743 2013; Usher-smith *et al.*, 2017). This is despite our aim to develop an intervention
744 that would be very brief and limit the additional resources required, highlighting the
745 challenges of developing interventions that are likely to be both effective and widely
746 used.

747

748 Our use of behaviour change theory, reviews of existing evidence in the literature,
749 and expert opinion to guide the development of the content of the intervention
750 further enabled us to maximise the potential effectiveness. However, our approach
751 has its limitations. Firstly, when assessing the effectiveness of BCTs we used

752 evidence from systematic reviews in which meta-regression had been used to
753 identify which BCTs were more effective for achieving change in a given behaviour.
754 The use of meta-regression with study level information to make inferences about
755 individual level change relies on indirect comparisons and so is at risk of ecological
756 fallacy or aggregation bias. The relationships between BCTs and behaviour change
757 seen in these reviews may therefore not reflect the relationships between individual
758 BCTs and behaviour change in experimental studies. Most of the evidence on
759 effectiveness of BCTs also relates to individual behaviours, such increasing physical
760 activity while our intervention targets multiple behaviours.

761

762 Secondly, although we purposefully recruited a diverse range of healthcare
763 professionals with different roles and years of experience from both general practice
764 and lifestyle provider services, most general practices were from areas of low
765 deprivation, with patients predominantly of white ethnic origin. The views of the
766 healthcare professionals in this study may, therefore, not reflect the views of those
767 working in areas of higher deprivation or different ethnic backgrounds where there
768 may be additional pressures on healthcare professional time, language barriers, or
769 differences in patient understanding and beliefs. We also acknowledge that the
770 professionals who took part may have self-selected due to positive views about
771 health promotion.

772 We also took examples of the components of the prototype intervention to the focus
773 groups and interviews. While this provided a springboard for discussion and we were
774 able to collect both positive and negative feedback on our prototype versions, it may

775 have made it harder for participants to consider what was really important to them
776 and they may have been more reluctant to voice contradictory opinions.

777

778 Thirdly, we chose to focus on the views of healthcare professionals rather than
779 patients. While this meant we did not include feedback directly from patients on the
780 intervention during this developmental stage, we did consider the patient
781 perspective throughout the process. This included working closely with our two
782 patient and public representatives, considering patient views within the wider
783 literature, and previous qualitative work with patients on the provision of risk-based
784 cancer information(Usher-Smith *et al.*, 2017). Patient feedback will be a central
785 component of future work piloting the intervention.

786

787 Although not necessarily limitations, the iterative nature of the intervention
788 development also brought with it a number of challenges. Involving over 60
789 healthcare professionals in the process meant we heard multiple, and in some cases
790 conflicting, perspectives on the intervention and received a large number of
791 suggestions for changes. In some cases the decision to implement a change or not
792 was straightforward. These included changes that were limited by practical
793 constraints, such as the suggestion to print the patient information in colour within
794 the consultation, and features that the healthcare professionals consistently thought
795 would be difficult to implement, such as assessing daily rather than weekly alcohol
796 intake. At other times, however, it was a challenge to decide when to implement a
797 change based on their feedback and when not to. For example, we chose not to
798 include the possibility to view the risk factor information of the average person

799 rather than the recommended lifestyle guidance. In these cases we tried to balance
800 what the majority of participants would benefit from as a reference point.

801

802 The potential time and cost of multiple iterations of changes to a digital intervention
803 was also a challenge as we were working with a computer programming team to
804 develop the website(Yardley *et al.*, 2015). We addressed this by developing a close
805 collaboration with the programmers from the start and arranged for them to train
806 one of the research team to make minor alterations without needing to go back to
807 them each time. We also took screen shots of potential pages from the intervention
808 to the early focus groups and interviews rather than developing the website at that
809 stage. Despite this though, the process was time-consuming and the potential risk of
810 overspend significant so it is an important consideration for others developing digital
811 interventions.

812

813 **Conclusions**

814 In conclusion, we have described how using NPT prospectively alongside behaviour
815 change theory and reviews of the published literature can be successfully used to
816 develop an evidence-based personalised cancer risk based intervention to provide
817 information and promote behaviour change in primary care. Healthcare
818 professionals involved in the delivery of prevention activities welcomed the
819 intervention and provided essential feedback for its refinement. The next step is to
820 pilot the intervention with patients and healthcare professionals within primary care
821 consultations. Recognising that implementation is an on-going iterative process
822 rather than a linear one(Damschroder *et al.*, 2009), a key element of that evaluation

823 will be working with healthcare professionals to help them adapt the intervention to
824 their practice. Central to supporting that process and preparing for the future scaling
825 up of the intervention will also be an evaluation of the potential unintended
826 consequences of the intervention and developing ways of working with healthcare
827 professionals to support them to overcome implementation challenges(Paina and
828 Peters, 2012).

829

830 **FIGURE LEGENDS**

831 Figure 1: Development and testing process of the prototype intervention

832 Figure 2: Usability testing results

833

834 **ABBREVIATIONS**

835 BCT- Behaviour Change Technique

836 CVD- Cardiovascular Disease

837 GP- General Practitioner

838 HCP- Healthcare Professional

839 MRC- Medical Research Council

840 NHS- National Health Service

841 NICE- The National Institute for Health and Care Excellence

842 NPT- Normalisation Process Theory

843

844 **DECLARATIONS**

845

846 **Ethical approval and consent to participate**

847 The study was approved by the Psychology Research Ethics committee of the
848 University of Cambridge on 25th May 2017 (REF: PRE.2017.043) and the Health
849 Research Authority (REF: 224443) on 15th May 2017. Written informed consent was
850 obtained from each participant.

851

852 **Consent to publish**

853 Not applicable.

854

855 **Availability of data and material**

856 All the data will be stored in accordance with the Data Protection Act 1998 within
857 the University of Cambridge data repository (<https://www.repository.cam.ac.uk/>) for
858 at least 10 years from the last access. All anonymised data will be publicly available
859 via that repository with links. Focus group and interview transcripts containing
860 pseudo-anonymised data will be stored in the repository and formal requests for
861 access will be considered via a data sharing agreement that indicates the criteria for
862 data access and conditions for research use and will incorporate privacy and
863 confidentiality standards to ensure data security.

864

865 **Competing interests**

866 None of the authors have competing interests.

867

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874

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876 data collection, analysis and interpretation of data; in the writing of the report; or
877 decision to submit the article for publication.

878

879

880 **Author contributions**

881 JUS, KM, SS and SG were involved in the design of the study. KM and JUS completed
882 data collection. KM, JUS, SS and SG contributed to the analysis and interpretation of
883 the data. KM and JUS wrote the first draft of the manuscript. All authors critically
884 reviewed the manuscript and have approved the final version.

885

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894

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1091 **Appendices:**

1092 1. Focus group / interview schedule

1093 2. Online feedback questionnaire including revised NOMAD checklist

1094 3. One page of lifestyle questionnaire

Table 1. Applying Normalisation Process Theory to development of the intervention

NPT construct and components	Description*	Considerations for prototype intervention design/delivery
<i>Coherence</i>		
Differentiation	Whether the intervention is easy to describe to participants and whether they can appreciate how it differs or is clearly distinct from current ways of working	Make the intervention simple to describe, with visual elements for ease of comprehension and completion. Host on a standalone website so not to interfere with current software in practice.
Communal specification	Whether participants have or are able to build a shared understanding of the aims, objectives, and expected outcomes of the proposed intervention	Align the aims, objectives and expected outcomes (i.e. to promote behaviour change to prevent disease) with those for NHS Health Checks and other prevention activities in primary care and make these clear in the training for the intervention.
Individual specification	Whether individual participants have or are able to make sense of the work – specific tasks and responsibilities – the proposed intervention would create for them	Provide clear guidance and training on delivery of the intervention. Limit the additional work delivery will create for individuals by developing a leaflet and website that patients can refer back to after the consultation.
Internalisation	Whether participants have or are able to easily grasp the potential value, benefits and importance of the intervention	Design to fit initially within current prevention activities within primary care, such as NHS Health Checks and chronic disease reviews.
<i>Cognitive participation</i>		
Initiation	Whether or not key individuals are able and willing to get others involved in the new practice	Engage with both those delivering the intervention and their managers/employers and include of clear justification for the importance of focusing on behaviour change for cancer prevention and parallels with other existing activities within the practice.
Legitimation	Whether or not participants believe it is right for them to be involved, and that they can make a contribution to the implementation work	Distinguish between the benefit of providing risk information and the role of face-to-face communication within the intervention to enable healthcare professionals to see the added value they provide.
Enrolment	The capacity and willingness of participants to organise themselves in order to collectively contribute to the work involved in the new practice	Structure the intervention to minimise the need for re-organisation or additional capacity and do not attempt to develop a standardised process for

		delivery to allow healthcare professionals to adapt it to different consultations and patient groups.
Activation	The capacity and willingness of participants to collectively define the actions and procedures needs to keep the new practice going	Work with healthcare professionals throughout the implementation stage to help them adapt the intervention to suit their local context and provide regular feedback.
Collective action		
Interactional workability	Whether people are able to enact the intervention and operationalise its components in practice	Consideration for the length of time needed to deliver the intervention to minimise impact on current consultation length.
Relational integration	Whether people maintain trust in the intervention and in each other	Ensure it fits with the overall objectives and current prevention activities such as NHS Health Checks.
Skill set workability	Whether the work required by the intervention is seen to be parcelled out to participants with the right mix of skills and training to do it	Design of the intervention to be simple and navigation intuitive to minimise staff requirement for training before use.
Contextual integration	Whether the intervention is supported by management and other stakeholders, policy, money and material resources	Inclusion of managers in focus groups/interviews and usability testing, to obtain their views on aspects of the prototype design and its delivery to establish potential resource and support constraints.
Reflexive monitoring		
Systematization	The collection of information in a variety of ways to seek how effective and useful for participants in any set of practices may seek to determine how effective and useful it is for them and for others, and this involves the work of collecting information in a variety of ways	Collection of data from key individuals in a variety of formats including both qualitative and quantitative methodologies.
Communal appraisal	Whether participants work together, formally or informally to evaluate a set of practices.	Provide participants with the opportunity to adapt the intervention collectively and evaluate the potential impact of the intervention in their own setting.
Individual appraisal	Whether participants in a new set of practices also work experimentally as individuals to appraise its effect on them and the contexts in which they are set. From this individuals express their personal relationships with the new set of practices.	Provide opportunities for key individuals to provide feedback in the planning and development of the intervention to facilitate design for incorporation into normal practices.
Reconfiguration	Appraisal work by individuals or in groups lead to attempts to modify practices.	For potential to adapt after initial usability testing.

*From Normalisation Process Theory Toolkit

Table 2: Evidence used to inform choice of format of risk presentation

Finding	Inclusion in prototype intervention design/delivery
<i>Pilot work with members of the public and healthcare professionals</i>	
When presented in colour, the colour was often more important than the number and dominated their interpretation.[37]	Inclusion of colour in risk presentation while ensuring that the colour scheme reflects current evidence / expert opinion.
Being able to see the impact of changes in lifestyle on their risk was helpful. This included the effect of small changes (increasing fruit and vegetable consumption by one portion per day rather than meeting the requirement of 5 portions per day). Some also wanted to be able to see the benefits they were already achieving through their current lifestyle. [37]	Incorporation of ways to demonstrate continuous change, both positive and negative, for each modifiable factor.
The first reaction of almost all when presented with their 10-year risk of an individual cancer was that it was low and not concerning, with views on what constituted a high risk ranging widely, from 0.5 to 60%. As a result, reductions in risk were not always motivating - the risks were considered low and differences small. [37]	Provision of combined risk of multiple cancers.
<i>Review of published literature and best practice guidance</i>	
Numerical presentation of risk as opposed to simple risk categories (moderate, high, low) appears to lead to more accurate risk perception[38] and when investigating only the patient’s preferences towards cancer risk communication, the majority of the British women and 50% of the Australian women expressed their preferences for quantitative risk information[39].	Inclusion of option to see risk as a percentage.
There were strong objections to the word ‘absolute’, which was seen as ambiguous. For many participants it conveyed that the risk score was ‘conclusive’, or in some way ‘definite’ that a person would suffer a cardiovascular event rather than a probability[40,41].	Avoidance of the term ‘absolute risk’ and clarity throughout that risks are estimates and apply to people with the same characteristics as the individual rather than the individual person.
People need comparisons between the probabilities of different risks in order to be able to interpret absolute risk information[39][41].	Provision of relative risk in addition to absolute risk information and comparison to individuals with a recommended lifestyle.
Presenting relative risk as number alone has been criticized as many participants did not know how to translate 2.3 times in absolute terms[42] or because it was “too alarming because the risks appeared bigger”[43]	Inclusion of option to see risk as an absolute percentage and comparison with individual with recommended lifestyle
Treatment decisions are sensitive to the way a treatment’s effectiveness is presented. The relative risk reduction format appears to encourage the treatment the most and number needed to treat format leads to the least acceptance[38].	Presentation of relative risk to encourage behaviour change.
Shorter timeframes (less than 10 years) may lead to more accurate risk perceptions and increased intention to change behaviour, than 10-year risk or longer, especially for older patients[38]. Some participants thought 10 years was too remote[41].	Decision made to present 10-year risk to be consistent with cardiovascular disease within primary care.

Display of risk information visually can enhance understanding compared with written information alone, particularly amongst those with low numeracy [47]	Display risk information with a simple visual for ease of understanding.
Graphical formats are perceived as helpful[41] but one format does not fit all[42]. Several formats were reported as confusing, such as line graphs, and icons, particularly those with larger numbers[41].	Inclusion of graphical presentation but avoid line graphs and icons.
People found formats which combined information helpful, such as colour, effect of changing behaviour on risk, or comparison with a healthy older person[41].	Inclusion of colour, effect of changing behaviour and comparison to individual with a recommended lifestyle.
Provision of feedback from the consultation to the counselee appears to be welcomed and the interest in other tools that complement the consultation has been pointed out (e.g. leaflets, CDs and other media to promote self-help etc.) including the tailored print communication through a personal letter summarising the consultation for the counselee[44].	Inclusion of option to print a tailored information sheet summarising the risk assessment.
Several explained they might take their risk more seriously if they knew exactly what the calculation is based on and how the numbers affect the final percentage[44].	Provision for individuals to change all the modifiable factors to see how that changes the final risk estimate and provided information on the development of the risk score as additional information.
<i>Consultation with experts and PPI members</i>	
To enable understanding of risk, incorporation of colour into the risk presentation. For this to be of use it must have meaning.	Inclusion of a colour scale from green to red to demonstrate level of risk where green corresponds to a relative risk of ≤ 1 and then the colour changes gradually to be orange at a relative risk of 2 and then to red at a relative risk of 4
Use of relative risk is acceptable in the context of this study, however this must be made clear to the recipient.	Clarity throughout that risks are estimates and apply to people with the same characteristics as the individual rather than the individual person.

Table 3. Selection of behaviour change techniques

Behaviour change technique (BCT)*	Description	Evidence for effectiveness **	Relevant to context	Practical criteria	Inclusion in prototype intervention design/delivery
<i>Goal setting (behaviour)</i>	<i>Set or agree a goal defined in terms of the behaviour to be achieved</i>	✓✓-	✓	✓	<i>Statement in introduction about benefits of goal setting/action planning and examples and space to include their goals</i>
<i>Problem solving</i>	<i>Analyse, or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators</i>	✓✓- x	✓	✓	<i>Statement on support page of leaflet</i>
<i>Goal setting (outcome)</i>	<i>Set or agree a goal defined in terms of a positive outcome of wanted behaviour</i>	✓	✓	✓	<i>Statement in introduction about benefits of goal setting/action planning and examples and space to include their goals</i>
<i>Action planning</i>	<i>Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity)</i>	-	✓	✓	<i>Statement in introduction about benefits of goal setting/action planning and examples and space to include their goals</i>
Review behavioural goal(s)	Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement.	✓✓-	✓	x	---
Review outcome goal(s)	Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement.		✓	x	---
Feedback on behaviour	Monitor and provide information or evaluative feedback on performance of the behaviour.	✓	✓	x	---
<i>Self-monitoring of behaviour</i>	<i>Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy</i>	✓✓	✓	✓	<i>Statement in lifestyle advice page on physical activity, with reference to the use of pedometers for self-monitoring</i>
Feedback on outcome(s) of behaviour	Monitor and provide feedback on the outcome of performance of the behaviour.	✓	✓	x	---
<i>Social support (unspecified)</i>	<i>Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues or staff) or non-contingent praise or reward for performance of the behaviour.</i>	✓✓-	✓	✓	<i>Statement in introduction describing how social support can be helpful to achieve changes in lifestyle with examples</i>
<i>Social support (practical)</i>	<i>Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues or staff) for performance of the behaviour.</i>		✓	✓	
<i>Information about health consequences</i>	<i>Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour</i>		✓	✓	<i>Risk of developing cancer with different lifestyles described verbally and visually with risk presentation</i>

Information about social and environmental consequences			✓	✓	Statement on saving money on quitting smoking page of leaflet
Social comparison	Draw attention to others' performance to allow comparison with the person's own performance	-	✓	✓	Comparison to someone with a recommended lifestyle included in risk presentation
Prompts/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.	-	✓	x	---
Behavioural substitution	Prompt substitution of the unwanted behaviour with a wanted or neutral behaviour		✓	x	---
Habit formation	Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour		✓	✓	Statement within introduction about habit formation and the fact that this can take several months to develop
Habit reversal	Prompt rehearsal and repetition of an alternative behaviour to replace an unwanted habitual behaviour		✓	x	---
Generalisation of a target behaviour	Advise to perform the wanted behaviour, which is already performed in a particular situation, in another situation		✓	x	---
Graded tasks	Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behaviour is performed.	✓-	✓	x	---
Credible source	Present verbal or visual communication from a credible source in favour of or against the behaviour		✓	✓	Reference to Cancer Research UK and University of Cambridge 'experts' with further resources at the end
Pros and cons	Advise the person to identify and compare reasons for wanting and not wanting to change the behaviour.	x	✓	x	---
Comparative imagining of future outcomes	Prompt or advise the imagining and comparing of future outcomes of changed versus unchanged behaviour		✓	✓	Opportunity to change lifestyle and see impact on risk and for people to revisit the website and amend their risk factors in the future
Restructuring of environment			x	x	---
Avoidance/reducing exposure to cues for the behaviour	Advise on how to avoid exposure to specific social and contextual/physical cues for the behaviour, including changing daily or weekly routines		✓	x	---
Adding objects to the environment		✓	x	x	---

*Behaviour change techniques are ordered by the Taxonomy [7]. BCTs shown in bold are included in the intervention **Evidence for effectiveness. Each study reviewed is acknowledged by the following symbols: (✓) positive association; (-) no association; (X) negative association; (blank) BCT not included.

Table 4: Participant characteristics

Participant characteristics	Focus groups/interviews (n=65)	Usability testing/online questionnaire (n=22)
Gender		
Male	14	4
Female	51	18
Place of work		
Lifestyle provider	41	12
General Practice	24	10
Job role		
Health Coach/Trainer	33	6
Practice nurse	12	5
General practitioner	7	4
Manager	6	3
Healthcare assistant	3	2
Administrator	3	2
Nutrition student	1	0
Number of years' experience in this role		
<1 year	17	3
1-2 years	23	9
3-5 years	12	3
5+ years	13	7
Participant characteristics	Focus groups/interviews (n=65)	Usability testing/online questionnaire (n=22)
Gender		
Male	14	4
Female	51	18
Place of work		
Lifestyle provider	41	12
General Practice	24	10
Job role		
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General practitioner	7	4
Manager	6	3
Healthcare assistant	3	2
Administrator	3	2
Nutrition student	1	0
Number of years' experience in this role		
<1 year	17	3
1-2 years	23	9
3-5 years	12	3
5+ years	13	7

Figure 1: Development and testing process of the prototype intervention

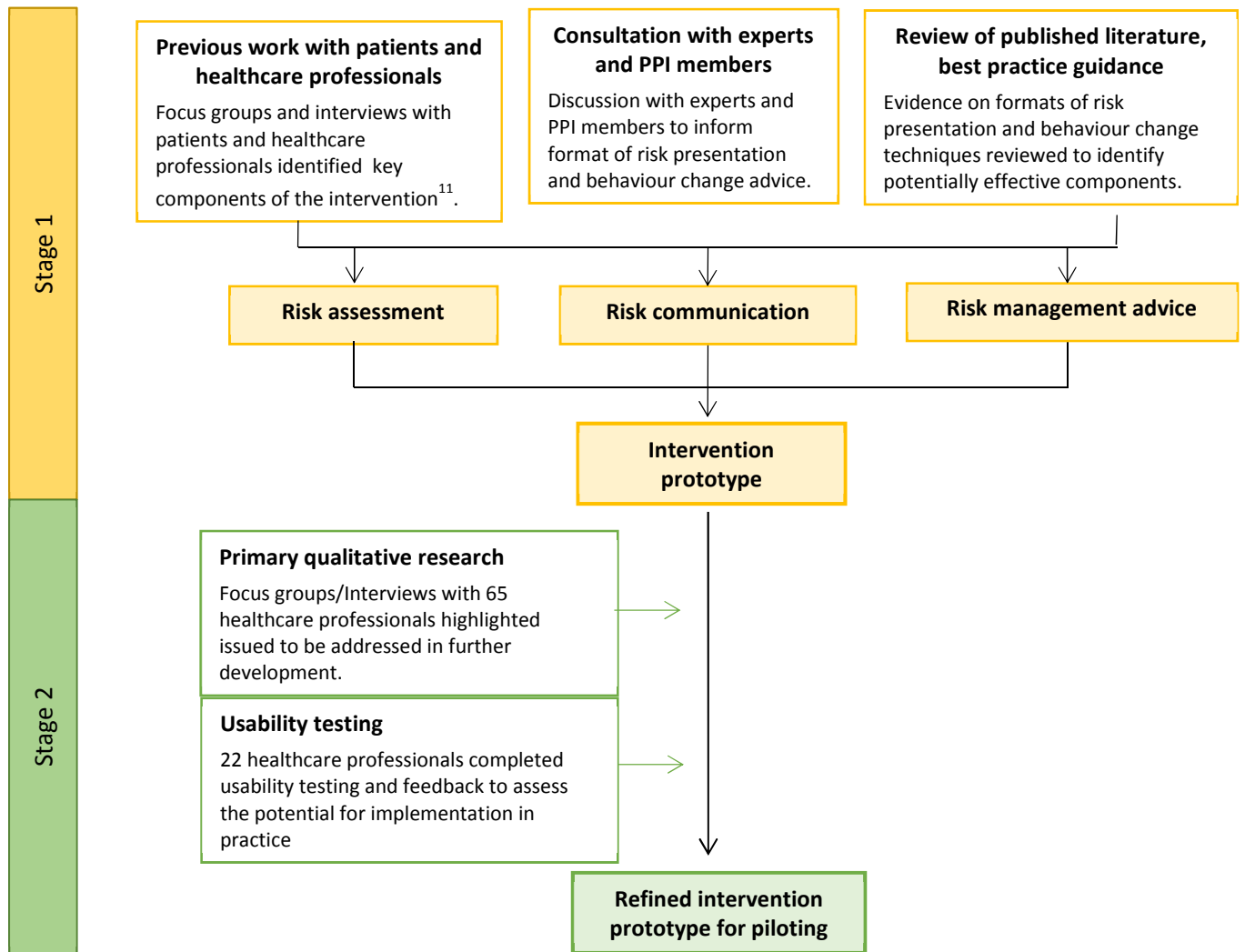
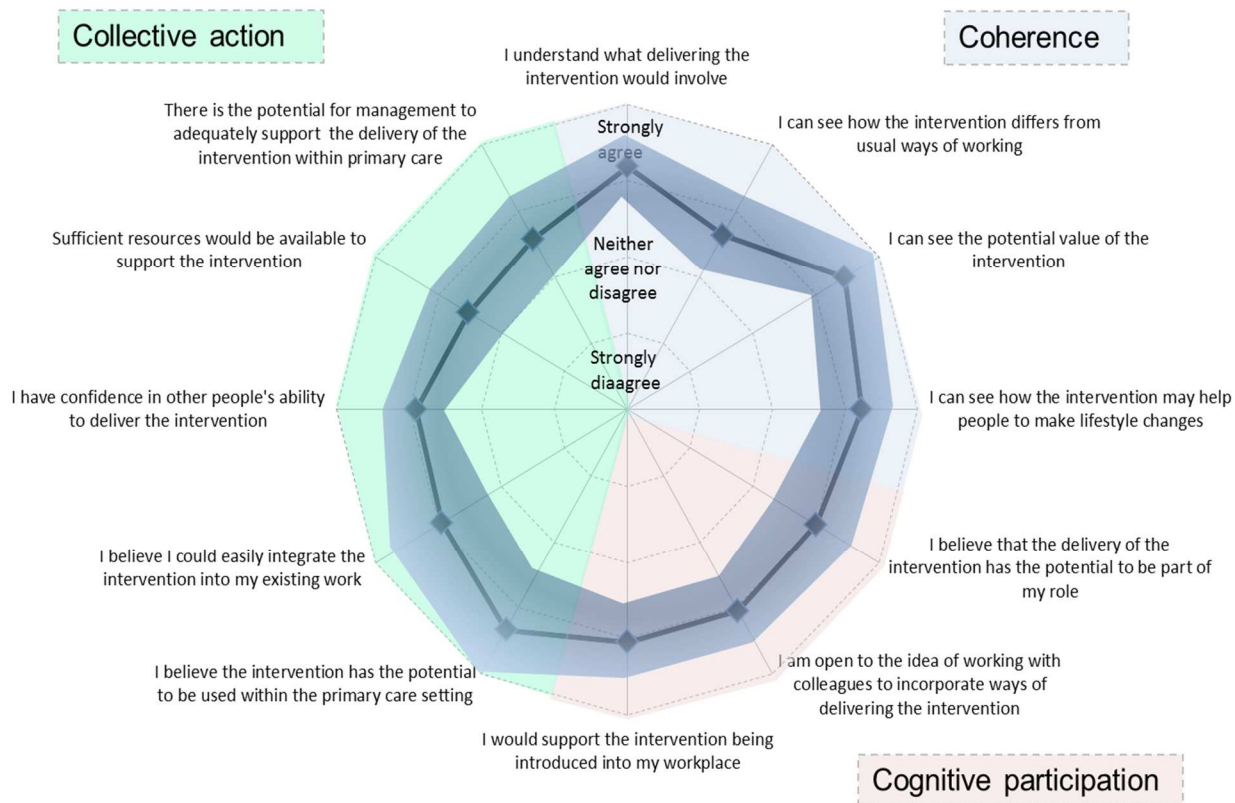
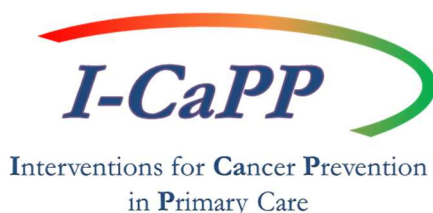


Figure 2: Usability testing results



Appendix 1: Focus group interview schedule



Introduction

Good morning/afternoon, everybody. My name is and this is my colleague [*Name of colleague*]. We both work on the Cancer Research UK I-CaPP research programme the University of The aim of this study is to develop very brief interventions incorporating cancer risk, which have the potential to help motivate people to change their lifestyle and their risk of cancer, which could be implemented within primary care. Thank you very much for helping us with this study. We're hoping to hear about your views and experiences regarding the sharing of cancer risk information and promoting behaviour change in the primary care setting. We have prototype brief interventions we would like to share with you. We'll invite you all to tell us your opinions or to share your experiences. There are no right or wrong answers. You might disagree with each other, or you might wish to change your minds in the course of the conversation. We would like you to feel comfortable telling us what you really think and how you really feel. It will be helpful if only one person talks at a time, as we're recording the conversation and when we listen to it afterwards it would be difficult to understand what people are saying if two or more people are speaking at once.

Anything that you want to say here can be said in confidence. We might quote some of the comments in our reports or publications, but if we do, we'll anonymise them so that people who aren't here today won't be able to identify who said what. We also ask you to maintain the confidentiality of what is said, so please don't talk about what anybody else has said after the meeting is over.

We expect the discussion to last around an hour. Please help yourselves to the refreshments and drinks at any time during the discussion.

I will be asking you the questions, and [*Name of colleague*] will be taking notes and making sure the recorder is working properly.

Before we start, can I ask you all to introduce yourselves? This introduction round will also be useful for us to check that our recorder can 'hear and record' everybody's voice. We'll check that and then we'll start the main discussion.

Prevention activities

I would first like to discuss with you the prevention activities that you are currently involved with, for example in NHS Health Checks or chronic disease reviews.

In these settings do you share risk information to patients? If so, would you be able to talk me through how you currently share this information...are there strategies that you use and have found work well or not so well?

When giving lifestyle advice are there also strategies that you use.

(Prompts: taking the patient through the leaflet, signposting to websites)

(Prompts: what you feel works well, not so well)

Do you feel that Cancer risk information could also be included in these settings?

(Prompts: if not, why not?)

Are you doing this currently?

Introduction to prototype interventions

We would like to share with you ### very brief interventions that we have designed for sharing cancer risk information and lifestyle changes that could be promoted to reduce cancer risk.

The first is....

The second is a booklet which includes information on the risk factors related to cancer, and has sections for goal-setting, which would be completed with the patient.

Please take some the time to look at these and consider their usability in your current workplace.

Prototype Discussion

If we could first talk about your overall thoughts on both interventions,

Now that you have had the opportunity to look at these, how familiar do they feel to you?

Do you feel either/both have the potential to become part of your normal work?

If we now look at the first intervention.

Do you feel you understand what delivering the intervention would involve?

Are there aspects that would differ from usual ways of working?

Is there potential value of the intervention?

How do you feel about its ability to help people to make lifestyle changes?

Does it have the potential to be part of your role?

Would there be the possibility to work with colleagues to incorporate ways of delivering the intervention?

Do you feel you would support the intervention being introduced into my workplace/role?

Do you feel the intervention has the potential to be used within the primary care setting?

Prompts: NHS Health Checks, Chronic disease reviews, Routine consultations

Do you think this intervention could be integrated into your existing work?

How long do you think it would take to deliver the intervention?

Do you feel confident in other people's ability to deliver the intervention?

Would there be sufficient resources available to support the intervention?

If applicable, is there the potential for management to adequately support the delivery of the intervention within primary care

Would you suggest any changes?

Please can we now move onto the next intervention....

Repeat the previous section of question for the next intervention.

Follow-up

We are interested to know about how patients are followed up after they have received risk information and lifestyle advice. Do you currently follow up patients? If Yes, how do you do this?

If no, do you feel this is something that might be beneficial to the patients?

Would text messaging be feasible for this?

Or perhaps a phone call from the practice?
Or a letter?

Closure

Short summary of the views: It appears that some of you think.... And others think... and we also heard that.....

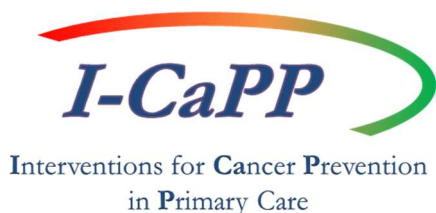
Is there any other information regarding your views on the provision of services for cancer lifestyle risk advice that you think would be useful for me to know?

If you later think of something that you would like the research team to take into consideration then please contact us on the email in your information leaflet.

Thank you very much for coming today. Your willingness to give up your time is very much appreciated and your comments have been very helpful.

What will happen now is that the tape-recorded file will be sent to an external transcriber who is working with us, they will transcribe it and send us the transcript back and then delete the audio files.

Appendix 2: Online feedback questionnaire including revised NOMAD checklist



Please tick
each box

I confirm that I read and understood the participant information leaflet (version 1, 24th March 2017) before participating in the focus group/interview. I have had the chance to think about the information and contact the study team to ask questions.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

I understand that anonymous direct comments from this questionnaire may be published in journals or presented at conferences, but without my name or other identifying details used, I give permission for my comments to be used for that purpose.

By clicking 'I agree' below you are indicating that you have read and understood this consent form, and agree to participate in this research study.

I agree

This survey is designed to gain a better understanding of the most effective ways to discuss cancer risk and prevention in primary care.

We understand that people have different roles, and that people may have more than one role.

From the statements below please choose an option that best describes ***your main role*** in relation to the prevention services:

- I am involved in managing or overseeing prevention services e.g. NHS Health Checks**
- I am involved in delivering prevention services e.g. NHS Health Checks**
- I am involved in commissioning prevention services e.g. NHS Health Checks**

For this survey, please answer all the statements from the perspective of this role. Depending on your role or responsibilities, some statements may be more relevant than others.

You will be prompted to look at each intervention in turn on the screen. This will remain open in another window while you complete the survey.

For each intervention you will complete 2 parts.

Part A includes two general questions about the intervention.

Part B contains a set of more detailed questions about the intervention. For each statement in Part C, there is the option to agree or disagree with what is being asked (**Option A**). However, if you feel that the statement is not relevant to you, there are also options to tell us why (**Option B**).

The final part to the survey, **Part C** asks some brief questions about yourself and your role.

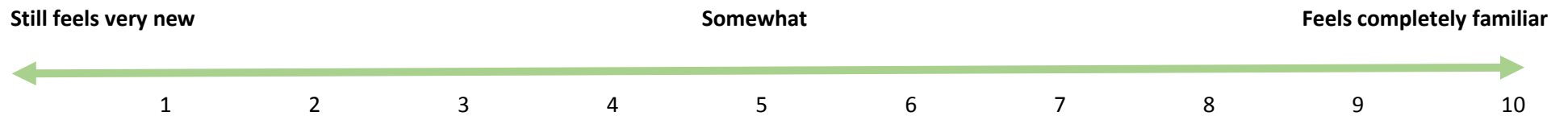
There is also a comments box at the end of the questionnaire if you would like to share additional thoughts about any of the interventions.

Please take the time to decide which answer **best suits your experience for each statement and tick the appropriate option.**

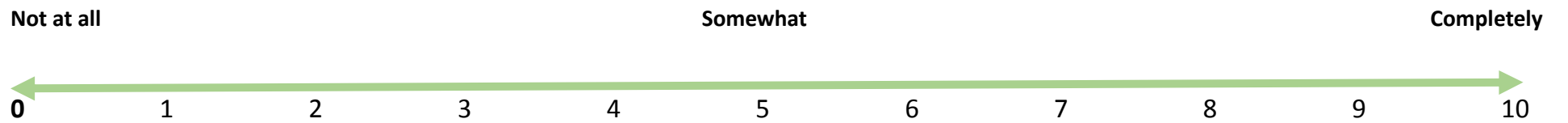
PLEASE LOOK AT INTERVENTION 1

Part A: General questions about intervention 1

1. Now that you have had the opportunity to view the intervention, how familiar does it feel?



2. Do you feel the intervention has the potential to become a normal part of your work?



Part B: Detailed questions about intervention 2

For each statement please select an answer that best suits your initial thoughts.

Section B1	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1. I understand what delivering the intervention would involve	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I can see how the intervention differs from usual ways of working	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I can see the potential value of the intervention	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. I can see how the intervention might help people to make lifestyle changes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

For each statement please select an answer that best suits your initial thoughts using **Option A**. If the statement is **not** relevant to you please select an answer from **Option B**.

Section B2	Option A					Option B
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Not relevant to my role
1. I believe that the delivery of the intervention has the potential to be part of my role	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I'm open to the idea of working with colleagues to incorporate ways of delivering the intervention	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I would support the intervention being introduced into my workplace/role	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

For each statement please select an answer that best suits your experience using **Option A**. If the statement is **not** relevant to you please select an answer from **Option B**.

Part C: About yourself

1. How would you describe your professional job category?

- Health trainer
- GP
- Practice nurse
- Health care assistant
- Health coach
- Manager of lifestyle services
- Public Health professional
- Other, please specify

2. How many years have you worked in this role?

- Less than one year
- 1-2 years
- 2-3 years
- 3-5 years
- 6-10 years
- 11-15 year
- More than 15 years

Additional comments

Please include any additional thoughts about the intervention here.

Thank you for completing our survey.

Eating more fruit & vegetables

Fruit and vegetables contain lots of important nutrients, which are vital for a healthy diet. They are low in calories and are an excellent source of fibre so can help you to keep at a healthy weight. Eating more fruit and vegetables can particularly help to reduce your risk of mouth, throat, lung and bowel cancers.



Fruit and vegetables

Experts suggest we eat 5 or more portions of fruit and vegetables each day. A portion is the same as a medium-sized apple, a handful of small fruit, or 3 tablespoons of vegetables.



“I try to eat 5 portions of colourful fruit and vegetables each day”

What changes could you make to include more fruit and vegetables in your diet?

Some ways that have worked for others include:

- ◆ Add fruit to your breakfast cereal
- ◆ Chop raw vegetables carrots, peppers, cherry tomatoes, cucumber sticks to snack on during the day
- ◆ Try adding a side salad to your lunch/dinner



- ◆ Include an extra portion of vegetables to your dinner
- ◆ Have a piece of fruit as your dessert each day

Fruit and vegetables

Use this space to write down your goal and plan how and when you will do your new action.

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