

## ORIGINAL ARTICLE

# Designing complex interventions: A description of the development of an intervention to reduce inequalities in planned dental visiting

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## Abstract

There are multifaceted reasons for a social gradient in planned dental visiting involving various psycho-social variables that interact with each other and the environment. Interventions in this area are therefore inevitably complex interventions. While guidance recommends undertaking theory and modelling work before experimental work is done, there is a shortage of descriptions of how this is done, especially in the field of oral health.

**Objectives:** To describe theory, qualitative and public engagement work, and identification of behaviour change techniques (BCTs) to define features of an opportunistic dental visiting intervention for adult users of urgent dental care services.

**Methods:** A systematic review and synthesis of theory, qualitative and quantitative work, along with expert input, generated a list of psycho-social determinants linked to planned dental visiting intentions. Modelling involved ethnographic work in urgent dental care settings and work with members of the community from the targeted demographic. This enabled verification, in the context of their idiosyncratic expression for the target population in question, of behavioural determinants (BDs) identified in the theory phase. It also facilitated generating intervention material which was infused with the identity of the end user. BDs identified were then mapped to BCTs using an accepted BCT taxonomy and an intervention prototype developed. The prototype then underwent iterative testing with target users before it was ready for a feasibility trial.

**Results:** Theory and modelling identified five key intervention focuses: affordable resources (time/ cost), the importance of oral health, trust in dentists, embarrassment of having poor oral health and dental anxiety. Short videos were developed to incorporate role modelling which were well received. Prototype testing resulted in shifting from 'if-then' plans to action planning.

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**Conclusions:** Complex intervention development involves an iterative rather than sequential process of combining theory, empirical work and user involvement, of which the article provides an example.

**KEYWORDS**

behaviour change, complex interventions, Dental attendance, implementation inequalities, intervention design, participatory research

## 1 | INTRODUCTION

Although spending on dental treatment is substantial,<sup>1</sup> an inverse care law operates, where those most in need are the least likely to benefit.<sup>2</sup> This offends the principle of distributive justice.<sup>3</sup> While it is arguable that health care contributes less to health inequalities than people's lifestyle and environmental factors, a social patterning of dental visiting is seen which means that dental service use contributes at least in part to oral health inequalities.<sup>4</sup> Promoting planned dental visiting is therefore an important strategy in reducing health inequalities.

McGinnis et al.<sup>5</sup> explain that the separate domains giving rise to health inequalities (social circumstances, environmental exposures, behavioural patterns and health care) rarely act in isolation, and it is in the intersections where these domains meet (such as between behavioural patterns and health care) which are particularly impactful. This provides both an opportunity for targeted action and a challenge, because of the complex nature of the interventions involved. Numerous studies have provided descriptions of reasons for avoiding dental care (barriers).<sup>6</sup> Psycho-social factors such as anxiety, cost and perception of need are common themes, although it is increasingly recognized that these rarely act independently of each other, but reciprocally interact and work in unison, like a 'web of effects'.<sup>7-9</sup> Therefore, to tackle the problem, we need to think about complex interventions.

Medical Research Council (MRC) guidance recommends taking a staged approach to the design and evaluation of complex interventions: starting with theory and then progressing to a modelling phase before experimental work is undertaken, although later versions of this guidance, emphasize that these phases should be seen more as iterative than linear (sequential) activities.<sup>10,11</sup> Since complex interventions work by introducing mechanisms that are sufficiently suited to their context to produce change,<sup>11</sup> there is a growing focus on paying attention, not just to the design of the intervention itself, but to the conditions which are needed to make an impact in the real world.<sup>12</sup> So, in line with understanding complex interventions as 'events in systems', user perspectives and understanding the context have become essential components in the design process.<sup>12,13</sup> This facilitates a deep understanding of users' knowledge, skills, behaviour, motivations and cultural background and also the setting concerned in order to shape the intervention while it is still under development, thus maximizing its relevance to users and feasibility of implementation.<sup>14</sup>

Insufficient attention to early design phases is said to result in weaker interventions that are harder to evaluate and less likely to be worth implementing. This is especially so where interventions are complex—as in most behaviour change interventions.<sup>15</sup> However, intervention development remains at an early stage with the majority of intervention study reports focused on reporting trial outcomes. Reports of theory and modelling phases are especially lacking,<sup>15</sup> particularly in the field of oral health interventions; so, this article aims to help address this gap.

Although literature describing socio-economic differences in dental visiting and associated barriers to care is plentiful, there is a dearth of intervention studies—which is surprising, given the importance of the problem and the fact that this issue faced by populations across the globe. The lack of intervention work in this area is probably due to the complex nature of the factors and interactions involved, making the design process problematic and so this article provides an example for researchers of how this can be done. It also provides some useful insights for policymakers and healthcare providers into the challenges and possible downsides of introducing interventions which aim to reduce health inequalities, exploring the 'fuzzy boundary' between an intervention and its context and how this might be handled in terms of design and anticipated in implementation. This article aims to describe the process of identifying key messages and design features of a planned dental visiting intervention. This involved integrating theoretical and systematic review evidence with qualitative work with problem-based dental attenders and the public.

## 2 | METHODS

### 2.1 | The role of theory

Various approaches to intervention development have been described from public health and social science perspectives, involving a range of frameworks from intervention mapping<sup>16</sup> to the more comprehensive Behaviour Change Wheel.<sup>17</sup> They have a common thread though, which is the combined use of theories and evidence and the integration of these with stakeholder perspectives. MRC guidance points to social science theory being an important starting point in identifying causal assumptions (the underlying mechanisms by which the intervention influences outcomes), although causal assumptions are also often informed by 'past experience and common

sense'.<sup>12,13</sup> Thus, while certain theories might be selected, these are open to adaptation when contextual information is taken into account. This places the approach more towards a problem-based behavioural science end of the spectrum which emphasizes 'addressing the problem using a multi-theoretical socio-psychological approach as opposed to a purely theory-driven applied behavioural science approach which focuses on testing a particular theory in an applied setting' (generating evidence on the validity of the theory in that setting).<sup>16</sup> Thus, a range of social psychological theories may be considered pertinent to the intervention and its implementation, and stakeholder involvement is an important component in both selecting what is pertinent, and refining an integrated product.

## 2.2 | Identifying intervention components and underlying mechanisms of change

The theory phase began with a systematic review which aimed to explain why inequalities in planned dental visiting arise and to identify appropriate intervention points.<sup>7</sup> It used critical interpretive synthesis as a review method because this enables an integration of quantitative and qualitative work and the development of theory. Dental and healthcare utilization theories were combined with qualitative and quantitative empirical work on barriers and enablers to planned dental care, and a theoretical framework generated which was structured accordingly in three layers: (1) the micro-level or individual level, (2) the meso-level or social processes and community structures, for example, social engagement; and (3) the macro-level or population-wide structures and policies, for example, the extent of public finance coverage. Micro-level factors were nested within but hypothesized to interact in a dynamic way with meso- and macro-level factors. However, since strategic approaches to intervention design recommend starting by prioritizing intervention points most amenable to 'practical intervention' and it was important to at least make a start somewhere—the scope for design was mainly focused on micro-level factors. Micro-level factors comprised a long list of psycho-social determinants linked to planned dental visiting intentions: (i) perceived oral health need, (ii) perceived seriousness, (iii) care efficacy, (iv) perceived vulnerability, (v) dental anxiety, (vi) self-efficacy, (vii) locus of control, (viii) fatalism, (ix) self-identity and (x) coping. Competing demands on people's lives such as time, stress, finance and co-morbidities, as well as service-related factors such as service availability and coverage were also theorized as counterbalances to motivations to seek planned care.

This is a similar premise to protection motivation theory (PMT) which explains health seeking behaviour as a counterbalance between a person's motivations to adopt healthy behaviour and the degree to which they feel able to adopt the behaviour, and whether they view the effort as worthwhile.<sup>18</sup> Rogers portrays this as parallel appraisal processes: threat appraisal and coping appraisal, with the balance between the two processes determining whether the individual adopts either a protective, or adaptive health behaviour (i.e. visiting the dentist for a check-up)—or a maladaptive strategy

(i.e. avoiding or procrastinating about dental visits), [Figure 1](#). PMT theorizes that threat appraisal variables comprise perceived severity of the health threat (e.g. experiencing toothache), perceived susceptibility (vulnerability) and fear of the health threat; whereas, coping appraisal variables comprise self-efficacy and response efficacy.

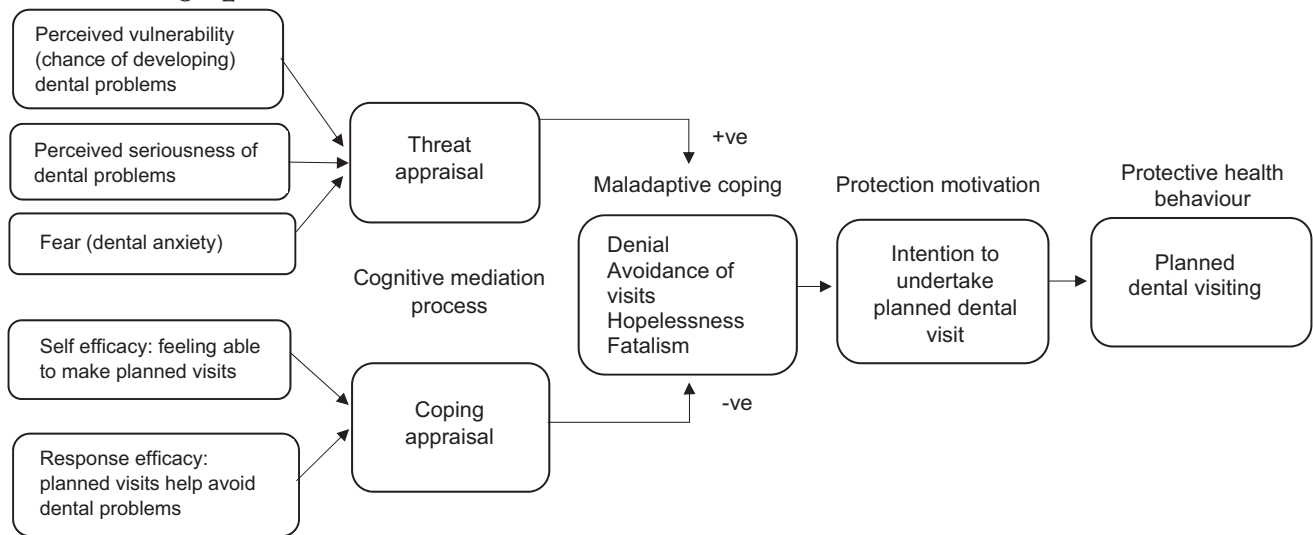
However, while most PMT interventions take the form of health leaflets/booklets containing messages targeting change in coping and threat appraisal variables, some limitations have been found, and this is attributed to PMT being limited to changing motivational variables which is merely the first phase/step in behaviour change; so augmentation involving a specification of goals is recommended (a volitional intervention).<sup>19</sup> Volitional interventions involve forming a specific plan, like an implementation intention which links cues to action ('If I receive a text message from a dental practice, then I will attend a dental appointment'); or an action plan (a plan outlining when, where and how to act).<sup>20</sup>

The research team also identified identity-based motivation theory (IBM), a further social psychological theory of human motivation and goal pursuit as relevant. This has been previously applied to interventions reducing socio-economic differences in health behaviour with some promise.<sup>21</sup> IBM explains when and in which situations people's identities or self-concepts will motivate them to take action towards their goals. It predicts that if an activity (e.g. dental visiting) is seen as 'identity congruent', difficulty is interpreted as meaning the behaviour is important, whereas if the behaviour feels 'identity incongruent', the same difficulty is interpreted as 'pointless' and 'not for people like me'.<sup>21</sup> Thus ensuring that images, stories and language within the intervention material were culturally relevant was important, not just to ensure acceptability to the user group, but to infuse intervention references to the behaviour (dental attendance) with a positive tone of identity relevant to the users' 'in group'. Community engagement and user co-production were therefore critical in getting messaging to resonate with the target group.<sup>14</sup>

## 2.3 | The modelling phase

This involved developing and testing theoretical concepts outlined above in the context in which they were to be applied. Key aims were to clarify key elements of the intervention and their interactions and make necessary adaptations to ensure that the intervention fully anticipated the priorities and needs of users. Modelling involved an ethnography in urgent dental care (work stream 1, WS1) as well as work with members of the community from the targeted demographic (work stream 2, WS2). Ethical and research governance approval were obtained for data collection during both activities (18/NE/0061, IRAS ID 240819 [WS1] and the University of Liverpool ID 4021 [WS2]).

Ethnographic work gave insight into the cultural background, health literacy, experience of dental care and the relative importance of the intervention components identified in the theory phase for this group of users. Ninety-seven patients were interviewed while attending urgent dental care services, with

**Footnote:**

+ve: when Threat appraisal e.g. dental anxiety is high, this increases Maladaptive coping (e.g. avoidance of dental visits)

-ve: when Coping appraisal e.g. self efficacy is high, this reduces Maladaptive coping (e.g. avoidance of dental visits)

**FIGURE 1** Protection motivation theory applied to planned dental visiting.

follow-up interviews undertaken with 19 of these some weeks later.<sup>8</sup> Thirty-nine (40.2%) were under 30 years of age, 45 (46.4%) were 30–49-years-old and 13 (13.4%) were 50 years-old+. Data collection also included 155 hrs+ of non-participant observation in urgent dental care services which was captured using field notes. Methods and participants' background characteristics are fully described elsewhere.<sup>8</sup>

While the ethnography in the intervention delivery setting provided data about the intervention setting and target users, this was supplemented by a wider set of qualitative work with members of the public of diverse age and gender and from diverse community settings to widen its social and cultural reach and to develop intervention features which may not have been previously considered or used in this context. Our work with users and potential users had both breadth and depth. We set up a study Facebook page linking in with closed community groups inviting discussion with: 'Do you just visit the dentist when you have a problem?' This prompted responses from 700 people, with 22 of these resulting in in-depth private chats online. Along with using local radio and newspapers, and other community work, for example, posters in local shops, Facebook helped recruit to a Community Advisory Group (CAG) of eight members. The CAG met as a group nine times over 16 months to discuss their experiences of dental visiting and intervention prototype material. A researcher also gathered views from a total of 110+ women and 225+ men by working in eight different settings in the local community. Community settings were selected to be representative of the target demographic of urgent dental care users. This included community settings involving

people experiencing unemployment, housing or benefit issues and poverty; young people with employability support needs; older people in various local communities; men in low job control work, for example, working in the building trade; and women in local community settings. Written informed consent was obtained from all research participants. Verbal consent was taken from those involved in the wider community work, and researchers were clear about the intentions of Facebook posts, that is, that these were being used for research purposes.

## 2.4 | Verifying relevant behavioural determinants and mapping to behaviour change techniques

Behavioural determinants (BDs) are the factors which explain individual and group differences in behaviour, while behaviour change techniques (BCT) are 'active components of an intervention designed to change behaviour' and are postulated active ingredients within the intervention,<sup>14</sup> for example, BCT goal setting (e.g. *if-then* or action planning) identified in our initial theory stage. Since dental visiting is a complex behaviour with many antecedents, several different BDs and associated BCTs are relevant. Relevant BCTs to be included in the intervention to address identified BDs were guided by the BCT v1 taxonomy which synthesizes expert opinion and evidence on what techniques are thought to be effective in changing associated theoretical BDs.<sup>22</sup> BCT codes used in the results section relate to this taxonomy. Following the initial theory stage, data

from WS1 and WS2 were used to refine a list of BDs and these were mapped to BCTs by one author (RH) to inform design of an intervention prototype. Then, using the prototype intervention material, a second author (RC) independently coded the intervention material using the same taxonomy to test the reliability of the mapping process.

The use of theory and behaviour change evidence at this stage allowed integration with emergent findings from WS1 and WS2, with iterative testing and refinement of hypothesized causal pathways and the identification of active ingredients of the intervention under development within the context concerned. Figure 2 outlines the cyclical and iterative processes involved with both theory and evidence gathered specific to the end users context, allowing development from a 'theory-inspired' intervention to a 'theory-based' one, with explicit causal pathways.<sup>23</sup> This included production of prototypes of elements of the intervention material and iterative testing and discussion with groups of target users.

## 2.5 | Iterative production of intervention prototypes and refinement of the draft intervention

As part of WS2, we shared iterative versions of the intervention and emerging material with people involved in our community work. This especially included significant numbers of men, and younger men (16–24 years) because WS1 observations found this group to be an important subgroup of urgent care users but who were also relatively difficult to engage in conventional interviewing in the urgent care setting (WS1). Data from these one-to-one and group discussions were recorded in field notes. The CAG also provided advice steering the language around intervention messaging.

## 3 | RESULTS

Table 1 summarizes how causal pathways of inequalities in planned dental visiting identified in the theory phase were translated and verified. This is illustrated using indicative quotes from WS1 and WS2. Quotes are coded to preserve anonymity using numbering of participants with a prefix denoting the type of site where the data were collected (DH = Dental hospital; FB = Facebook; DP = Dental practice; CAG = Community Advisory Group member). Combined theory and modelling identified five main barriers to dental attendance: (1) affordable resources (time and cost), (2) the importance of oral health, (3) trust in dentists, (4) embarrassment of having poor oral health and (5) dental anxiety. The project team discussed developing intervention material containing material for all five barriers in one pack with separate sections, but WS2 work gave a clear steer towards producing easily digestible 'chunks' of information with a narrower focus, and so six separate booklets were produced (dividing 'affordable resources' into time and cost barriers). This was necessary, not only to reduce information burden for users but also to produce a brief intervention which could be delivered opportunistically within about 15 min.

Theory and modelling identified social influences and self-identity as important behavioural determinants, with role modelling a relevant BCT for all five barriers (Table 1). Short (2–3 min) videos were produced to address each barrier, spoken to camera by someone who was seen as being authentic and from the local community, ensuring that this included a range of gender, age and ethnicity pertinent to the demographics of urgent dental care users. A rounded understanding of this was developed in WS1 and WS2. Several of the intervention videos featured people who had engaged with our community-based work or were members of the

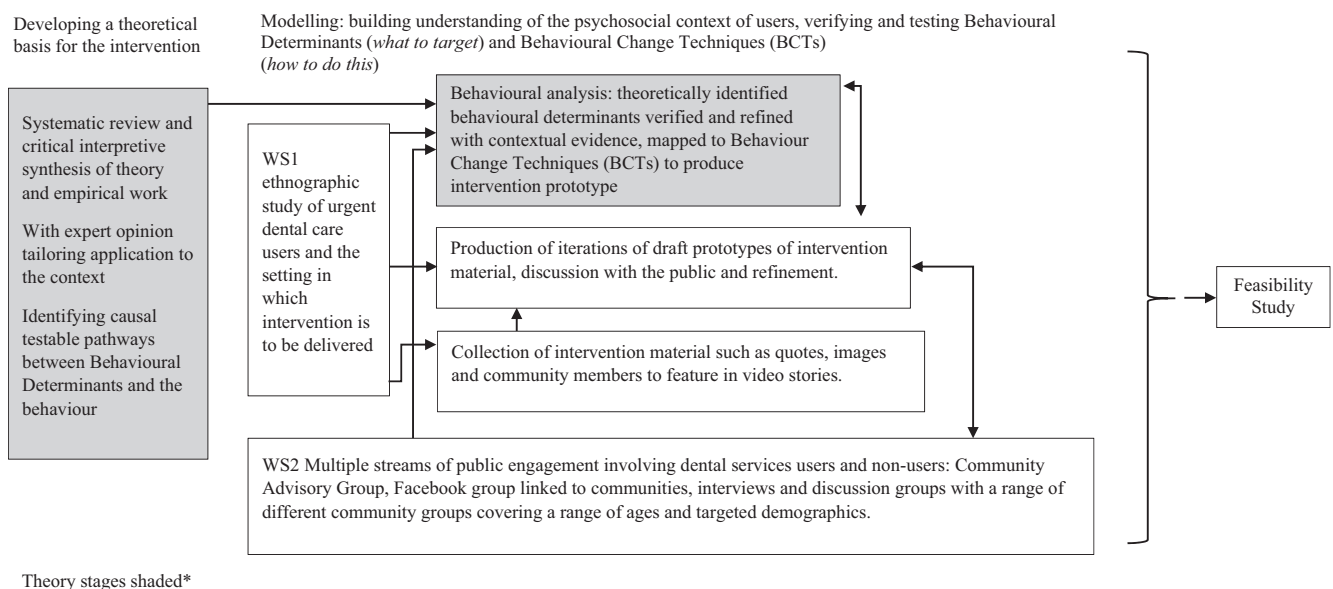


FIGURE 2 Overview of the intervention development process. WS, workstreams.

TABLE 1 Integration of theory and modelling phases to inform intervention design.

Barrier	Review and synthesis of theory <sup>7</sup>	Qualitative data from modelling phase	Theoretical domain for behavioural determinant	Behaviour change techniques from BCT taxonomy v1	Behaviour change technique applied to define intervention approach, features and key messages addressing the problem (Some are common to several barriers and so are numbered to show where there are overlaps)
<b>Affordable resources</b> (time, money, including shift work, or manual type jobs where you only get paid for the work you do identified as a barrier)	Job security and poor job control	<b>Job control</b> DH01: 'They want to know everything about you - where you have been. I do shifts (morning and evening) depending on how the week was' [so it is difficult to meet appointments because of a lack of notice in his schedule] DH04: 'He just really does not like anyone being off, he wants everyone in work'. (talking about the boss at work) DP13: 'They'd [say I] would not get paid. Not a problem if I take a day off. Problem is to take more days off. Won't cost me money, will cost me my job.'	Environmental context and resources Beliefs about capabilities	Antecedents 12.5 adding objects to the environment Vicarious experience (modelling) (watching someone who you associate with, who has accomplished the behaviour) [6.1 - Demonstration of the behaviour] Verbal/social persuasion about capability (telling people that yes, they can do it) [15.1]	1. Signpost to services with evening appointments 2. A card to show boss that this is needed, and that regular dental care may lead to the need to take off time at short notice for emergencies 3. Video—story of someone who has this challenge and been able to do this. 4. Booklet material emphasizing capability 'Don't give up. You can change the appointment if you need to and make another for a few weeks time when things are easier'. 5. Follow-up text assures that 'Yes, you can do it, and well done if have taken an action in this direction'.
<b>Protection motivation/Competing demands</b>		<b>Relative prioritization of time and expenses</b> DH01: 'You've got to try and fit it in, because you are busy. Its bone idleness. I should be able to afford it'. FB20: 'An endless list really, where costs of things get prioritized over each other every month. Therefore, preventative treatment is rarely going to make it near the top of any list like that...' DP102: 'There's no point me coming today and getting it all sorted to not keep coming back and have it maintained. Otherwise it's a waste of my time today' <b>Knowledge about costs and availability</b> DH01 'I think it's like £30 or £40 just to stay with them'. DH03 'I don't even know what the costs are now. I've no idea....I'm only on a state pension'.	Motivation and goals Shaping knowledge	Goal setting of behaviour [1.1] Problem solving [1.2] Action planning [1.4] Encouragement and support [3.2 Social support practical] Framing/reframing beliefs about behaviour [13.2] Anticipated regret [5.5] Information about health consequences [5.1] Comparative imaging of future outcomes [9.3] Instruction how to perform the behaviour [4.1]	6. Goal setting 'I will make an appointment by'. 7. Identify someone who might support the actions for example, discuss with partner about budgeting. 8. 'Even though you'll have a lot of things to fit into your life, visiting the dentist before you have a problem would save you money and time in the long run'. 'Going for regular care is a lot cheaper than needing a lot of treatment later on'; 'You can find a dentist which fits in with your life'; 'Planning a visit will help you find time when its really difficult for you'. 9. Supportive conversation delivering the intervention—expressing empathy and letting the patient decide what will and will not work. 10. Information on cost of NHS treatment, that there is a maximum that some people get reduced costs. 'You can use some services at different times and also change it if you can no longer keep it'. 11. Make the information simple to access and simple to read to lower the information burden



TABLE 1 (Continued)

Barrier	Review and synthesis of theory <sup>7</sup>	Qualitative data from modelling phase	Theoretical domain for behavioural determinant	Behaviour change techniques from BCT taxonomy v1	Behaviour change technique applied to define intervention approach, features and key messages addressing the problem (Some are common to several barriers and so are numbered to show where there are overlaps)
Importance of oral health (lack of awareness that there may be a dental problem which needs care)	Perceived vulnerability (chance of developing) dental problems.	DH03: 'I keep my teeth in order you know. If I thought there was something wrong, I would go, but I've never had any bother'. DH02: 'And I kept brushing my teeth to keep them clean you know, and if I would have had a problem with me teeth or anything, I certainly would have gone'. DH04: 'No, cause it weren't hurting me so I didn't, like, I didn't know there was a problem'. DP01: 'I don't really pay attention, I just thought, I'll just keep brushing my teeth and cleaning them'. 'I didn't realise that then can lead into an abscess. If I had of got told that I probably would have kept a bit more of an eye on it'.	Beliefs about consequences	Information about the health consequences [5.1] Comparative imaging of future outcomes [9.3]	12. Information about chances of having a problem you do not know about 'Dental decay can be like an ice-berg where you only see a bit from the top and there might be quite a bit below'. 3. Video—story of someone who has experienced this.
Perceived seriousness of dental problems	DP103: 'I've watched YouTube videos of people with mouths, like, being destroyed. That makes you want to go to the dentist straight away'.		Social influences	Information about the health consequences [5.1] Social comparison [6.2]	13. Information on consequences of not having your teeth checked before you have a problem: 'People who don't see a dentist regularly are 4 times more likely to have lost some of their teeth.' 'The dentist also checks for mouth cancer'.
Trust in dentists and the dental system (beliefs as to whether attending the dentist will be worth it and actually avoid having problems in the future)	Response efficacy Self-efficacy	FB03: 'I badly need work doing so I can have my smile back but like most things in life when you av bad experience it puts people off an they lose faith bcoz i av no evidence that the person who is doing the job is gud or not ...' FB07: 'I have no faith in dentists or their competence from these experiences' DP37: 'I said I'm not going back to that one. Because I don't think he knows what he's doing'. DP06: A couple of years ago, about five, seven years ago, I seen a dentist and he said I needed two fillings. Then I seen another dentist and he said I don't need any fillings. So it put me off going to them. Corrupt dentists. Butchering people's teeth for cash. DP17: 'Because I thought I'd be going in for a check and the next thing I've got my tooth getting ragged out or a filling or something. So I just didn't have a clue'.	Shaping knowledge Social influences Beliefs about capabilities	Instruction how to perform the behaviour [4.1] Social Comparison [6.2] Action planning [1.4] Vicarious experience (modelling) (watching someone who you associate with, who has accomplished the behaviour) [6.1] - Demonstration of the behaviour]. Verbal/social persuasion (telling people that yes, they can do it) [15.1] Framing/reframing [13.2] Comparative imaging of future outcomes [9.3]	14. Information on how to take an active role in decision making: 'You can ask questions and take an active role in your care'; suggested questions and a script, for example, ask the dentist before any course of treatment how much it will cost. 15. Information to reassure on the veracity of information, for example, 'Here is where you can check what the practice is telling you'. 16. Graded task—with detailing action towards tackling the barrier, for example, writing a list of questions to ask the dentist or dental practice. 3. Video—story of someone who has this challenge and been able to do this. 4. Booklet material emphasizing capability: 'If it isn't helping you, you can walk away and use another dentist'. 5. Follow-up text assures that 'Yes, you can do it, and well done if have taken an action in this direction'. 17. Booklet material on possible alternative future 'Just because you had a bad experience with one dentist doesn't mean that it will be the same next time'; 'You don't have to have any treatment you don't want'.

(Continues)

TABLE 1 (Continued)

Barrier	Review and synthesis of theory <sup>7</sup>	Qualitative data from modelling phase	Theoretical domain for behavioural determinant	Behaviour change techniques from BCT taxonomy v1	Behaviour change technique applied to define intervention approach, features and key messages addressing the problem (Some are common to several barriers and so are numbered to show where there are overlaps)
Embarrassment (Feeling disempowered, approved of, shamed and judged)	Self-identity Coping Fear Self-efficacy	FB10: 'It started off as a bit of anxiety and not wanting to be disapproved of for cavities or not having straight teeth...' DH01: 'cos sometimes its embarrassing when you've got bad teeth... you don't want people seeing them'. Last time I was there two girls said 'They're not that bad, they're full of plaque.' Stoicism response (self-sufficiency coping) to anxiety DH03: husband 'I don't want a doctor, I don't want an ambulance. He took his own tooth out'. DP03: 'Giving meself a bit of a goal really, just being, erm, confident in being able to go the dentist by meself... you know to reach out and to be able to say, I need to come in, that sort of thing'.	Shaping knowledge Social influences Social role and identity Emotion Action planning Beliefs about capabilities	Framing/reframing [3.2] Encouragement and support [3.2 Social support (practical)] Social comparison [6.2] Identity associated with new behaviour [13.5] Anticipated regret [5.5] Action planning [1.4] Vicarious experience (modelling) (watching someone who you associate with, who has accomplished the behaviour) [6.1 - Demonstration of the behaviour]. Verbal/social persuasion (telling people that yes, they can do it) [15.1].	18. Booklet Information on 'Quite a few people feel like this, you aren't the only one'; 'Most people go into dentistry because they like helping people'; 'Your teeth may have been damaged a long time ago, but that does not mean to say nothing can be done about them now'. 16. Graded task/action plan detailing action towards tackling the barrier for example, Ring around some dentists and tell them your worry and see what they say. 7. Identify someone who might support the actions, for example, discuss with partner about budgeting. 3. Video—story of someone who has this challenge and been able to do this: 'You aren't the only one like this with poor teeth'. 4. Booklet material emphasizing capability: 'If it is not helping you, you can walk away and use another dentist (if you feel judged)'. 5. Follow-up text assures that 'Yes, you can do it, and well done if have taken an action in this direction'. 9. Supportive conversation delivering the intervention—expressing empathy and letting the patient decide what will and will not work.
Anxiety	Coping Fear Self-efficacy	FB09: 'I think my problem is a control thing. I feel so helpless when put in the reclining chair...' DP02: 'It's just fear. It's so painful. I hate needles, I hate anyone putting their hands towards me. And when you come to the dentist it's all of them things'	Shaping knowledge Beliefs about consequences Social influences Emotion skills Self-efficacy Action planning	Instruction on how to perform the behaviour [4.1] Social support practical [3.2]; Social Support emotional [3.3] Reducing negative emotions [11.2] Distraction [12.4] Focus on past success [15.3] Vicarious experience (modelling) [6.1—Demonstration of the behaviour] Verbal/social persuasion (telling people that yes, they can do it) [15.1] Action planning [1.4] Adding objects to the environment [12.5]	3. Video—story of someone who has this challenge and been able to do this: 'You aren't the only one like this with poor teeth'. 7. Identify someone who might support the actions, for example, discuss with partner about budgeting. 18. Booklet information on 'Quite a few people feel like this, you aren't the only one'; 'Suggestions for relaxation and distraction techniques such as listening to music; Making the first appointment in the day is a good thing' 16. Graded task/action plan detailing action towards tackling the barrier, for example, Talk to other people about how you feel about this'. 5. Follow-up text assures that 'Yes, you can do it, and well done if have taken an action in this direction'. 9. Supportive conversation delivering the intervention—expressing empathy and letting the patient decide what will and will not work. 19. Tear out sheet in booklet to give to the dentist to express their fear, and communicate their preferred stop signal, etc.



CAG. These video stories were also overlaid with an animation, the characters of which were then picked up in the accompanying written booklet material. This approach not only helped make the intervention engaging but also helped overcome limited literacy among some users. CAG members confirmed that these video stories were particularly meaningful, and also guided the tone as well as the content of material, ensuring we reflected the user 'in group' as authentically as possible (Table 2).

While goal setting and incorporating a volitional component into the intervention was identified as a key BCT in the theory phase, when we developed our prototype using an implementation intention (*if...then...*) approach, we found that while the target group were able to set a goal for a planned dental visit (e.g. *I will make a dental appointment before my brother's wedding next month*), they struggled to think and write about hypothetical future scenarios following the '*if...then...*' format as outlined by Gollwitzer.<sup>24</sup> We therefore shifted our approach and substituted this with an action planning approach (BCT 1.4)<sup>24</sup> which has a simpler format for planning.

Both theory and modelling stages identified building self-efficacy (beliefs about capabilities) as an important BD to target, which was common to the majority of barriers concerned (Table 1). According to social cognitive theory, there are four major information sources of one's self-efficacy: performance accomplishments, vicarious learning, verbal encouragement, and physiological and affective states.<sup>25-27</sup> We therefore sought to incorporate encouragement for taking small steps towards dental visiting goals by sending a text message a few days after intervention delivery, tailored around their personal action plans set at the time the opportunistic intervention was delivered. The action plan setting process was supported by a non-judgemental conversation with a trained dental nurse and included helping patients identify someone in their social circle or family who could support their efforts. Messages of verbal encouragement '*Yes, you can do this*', were also incorporated into the booklet material. Since research shows that while role models are effective in improving self-efficacy,

they need to be credible with the viewer, garnering attention and demonstrating the behaviour with coping rather than mastery, our video stories relating to each barrier were produced with this in mind.<sup>26</sup>

Both theory and modelling identified that addressing some factors external to the individual might help make planned dental visiting easier. In particular, we found that for some people in manual work, having a conversation with their boss about having time off for a dental appointment was difficult. During WS2, we explored this by visiting and talking to men working on a construction site and subsequently incorporated into the intervention, an 'employers card' (a credit-sized card with a clinic/hospital stamp which could be shown to the boss, emphasizing the importance of the appointment, and facilitating the conversation). We also included material within the dental anxiety barrier booklet which the patient could use to express their fear and as a written guide expressing how they would like their treatment to go, to be given to their dentist when attending an appointment (although this element was substantially reduced after the prototype phase in response to user feedback). Figure 3 provides a logic model which illustrates the relationship between identified BDs, intervention components and expected outcomes.

## 4 | DISCUSSION

Rigorous deployment of theory and modelling processes in design of complex interventions can give rise to a 'bewildering' menu of possible BCTs. There also often appears to be a lack of transparency explaining how certain BCT combinations are selected.<sup>14</sup> While qualitative research and/or expert and user consultation can be deployed to help address this, Yardley et al. argue that these methods are often applied in an ad hoc way and/or are poorly articulated.<sup>14</sup> Thus, a process for exploring and analysing the attitudes, needs and situation of the people who will be using the intervention is needed to inform the selection of intervention components that are the most acceptable, feasible and salient, while crucially also avoiding including elements that are disliked or seen as impractical or intrusive.<sup>14</sup> Our article outlines how this can be done by describing how we developed an intervention for a behaviour involving many different and interacting antecedents.

The intervention was designed to reduce inequalities in planned dental visiting. This means that a key purpose was to promote equity. Equity acknowledges that different individuals need different supports to attain similar results—as opposed to providing the same supports for everyone, which would only achieve equality (where sections of the population might remain worse-off). Therefore, recognizing that people from deprived communities are disproportionately poorer users of dental services, in both theory and modelling phases we sought to identify behavioural determinants which were important determinants of visiting behaviour especially in these populations. Subsequent refinement and work to incorporate the self-identity of users from more disadvantaged communities, meant that the intervention 'product' entering a feasibility trial, was as

TABLE 2 Example of Community Advisory Group (CAG) feedback guiding the content and tone of the intervention to reflect the user 'in group'.

CAG member code	Indicative quote
CAG06	<i>'And it makes it real as well. You've got someone talking about their personal experiences haven't you? And it's not a set-up....he's not reading from a thing is he. It felt real and genuine and important to him'. [Comment on video content]</i>
CAG05	<i>'Sometimes I find that the accent's very irritating when you hear it back to you'.</i>
CAG04	<i>'You know, somebody you can tell is from the area but doesn't necessarily go... at the end of everything they say. But you can still tell that they're from the area. They're still one of your people sort of thing'.</i>

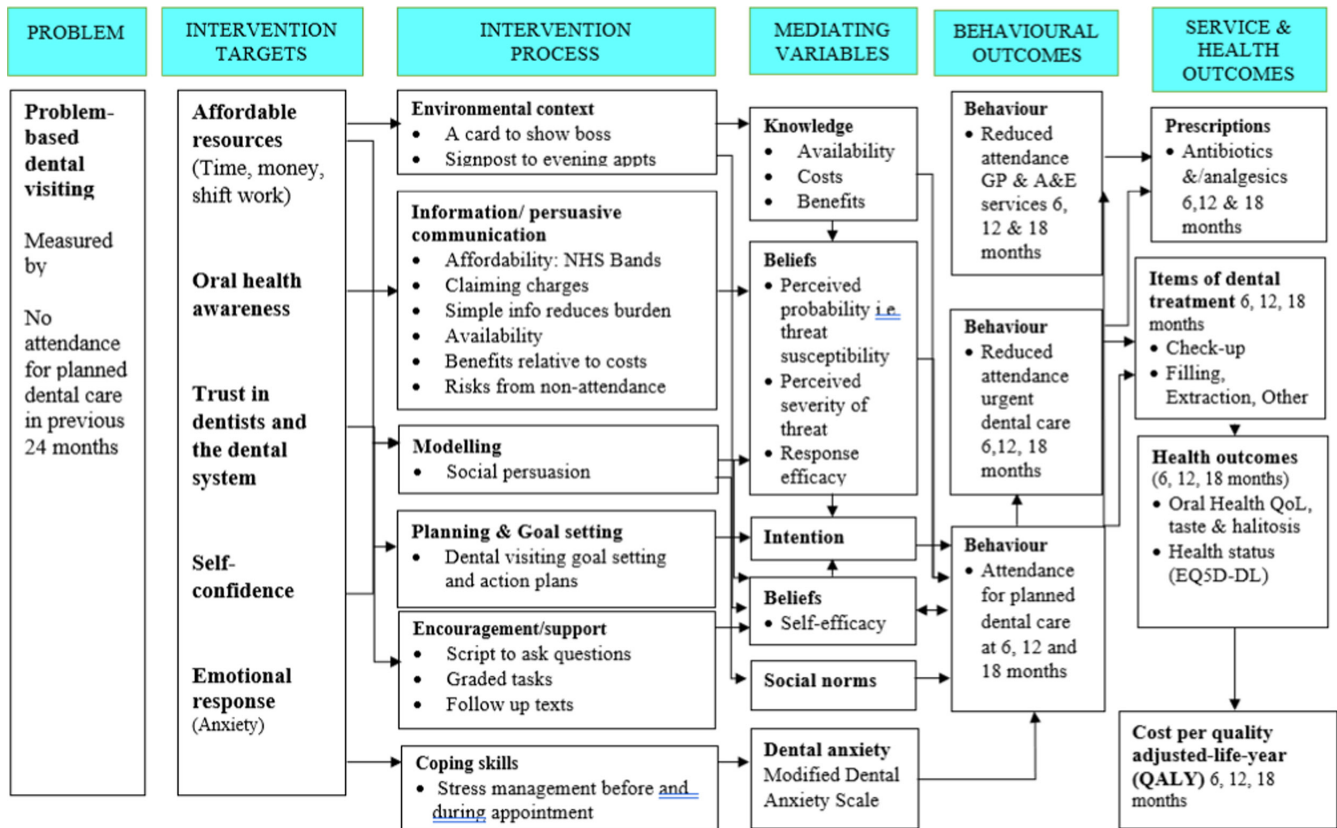


FIGURE 3 Logic model describing the relationship between behavioural determinants, intervention components and expected outcomes.

tailored to differentially supporting this demographic, as could be. Whether the intervention does indeed, not only promote planned dental visiting, but also reduces inequalities in this, will only be apparent when trial outcomes are evaluated, and this will be an important component of the final analysis.

It is possible that contextual factors may overwhelm the degree to which a mainly micro-level intervention can achieve equity. While the focus of our intervention was targeting individual-level BDs, we know that meso- and macro-level factors also shape people's behaviour and contribute to socio-economic differences in the use of dental services.<sup>7</sup> We found in our qualitative and public engagement work, expressions of collective patterns of attitudes and lifestyle shaped by structural factors such as class and gender. For example, we experienced perceptions of little agency over goals, reminiscent of 'short-time horizons' and limited personal autonomy in their lives typical of low socio-economic groups as described by Franklin et al.,<sup>28</sup> which meant that completion of a planning scenario such as 'if...then' was challenging. We adapted the planning approach accordingly and looked for ways to support the environmental context where possible. The card developed for participants to show employers to legitimize taking time off work for dental appointments is an example of where the intervention, although delivered to individuals, also addressed environmental macro-level factors such as employment policies which disadvantage those at the lower end of the social gradient. A key challenge for interventions aiming to address inequalities, is the extent which they can be practically

targeted and delivered while also acknowledging the reasons that socio-economic differences in health behaviours exist is rarely just down to the health behaviour knowledge, beliefs and motivation of the individuals concerned.

The intervention development work described represents the first stages of the design process. What is implemented and how, can impact outcomes further, and so the next phase of developing the intervention involves looking at how the intervention operates in the context in which it is delivered, which then allows further intervention refinements to be made before a clinical trial is undertaken.<sup>11,12</sup> Feasibility testing, with further qualitative work with healthcare providers and policymakers as well as with users, is an important next stage of the process. Although feasibility studies are set up with aims to address key areas of uncertainty before a clinical trial is undertaken, such as whether sufficient participants can be recruited to a trial in that setting within a reasonable time frame and come with a priori trial progression criteria; when the intervention starts to be applied in feasibility studies, this enables an investigation of what happens when the intervention is implemented in the setting and with the target group concerned. Aspects of the intervention and its delivery can be explored such as identifying optimal intervention content and delivery, acceptability, adherence and capacity of providers to deliver the intervention.<sup>12</sup> Wider stakeholders, including managers and policymakers also provide important perspectives at this time, especially regarding its implementation, likely cost-effectiveness and addressing issues which may hinder

future wider adoption. The product of this next phase is a refined, 'final version' intervention before its clinical effectiveness is tested in a clinical trial—although the effects of the implementation context will continue to be examined in this phase too, so technically this could be classified as a type 1 effectiveness-implementation hybrid trial design.<sup>29</sup>

Addressing implementation hand in hand with design work, is a key principle when trying to work with complex systems, because while the intervention design process informs what is implemented, what happens on implementation can change outcomes achieved by the intervention and thus what needs to be incorporated into the intervention and its delivery in order for it to be effective.<sup>30</sup> May et al. emphasize that when complex interventions are implemented in different contexts, the interaction between the intervention and the environment in which they are implemented can be dynamic and variable (depending on the context and the timing of when the intervention is implemented).<sup>31</sup> An example of this is the occurrence of the COVID pandemic just as the developed intervention progressed to the feasibility study stage (Figure 2). This brought a global disruption of routine dental services because of the risk of viral transmission which substantially altered local service capacity and access to NHS dental services, and which could not have been anticipated.<sup>32</sup> This meant that while at the outset of the process, there was relatively good coverage of available NHS dental services, this became more limited as time went by, and the relative importance of service-level factors grew—thus changing the context in which the intervention was applied. This illustrates one of the challenges of following a rigorous intervention design process, especially where it involves sequential stages of developing an intervention—the context in which it is placed is continually evolving—and potentially rapidly so.

While at the outset of the process, a logic model was constructed to map likely outcomes and the mechanisms involved, a dark logic model was not constructed because it seemed unlikely that there would be any significant adverse effects. Dark logic models theorize possible ways harmful consequences of the intervention can arise.<sup>33</sup> Public health interventions, especially those disrupting complex social systems are vulnerable to unintended consequences, and so dark logic models can be helpful in evaluating potential harms and the underlying mechanisms associated with their occurrence. In hindsight, given the change in context, a dark logic model would have been useful since, with a shift in context, 'paradoxical effects' now seem more possible. For example, the intervention incorporating a planning element which was designed to help facilitate planned dental visiting for people with low socio-economic backgrounds not used to structuring their time and priorities in that way, might expand health inequalities because people with more disposable time and energy may be more able to harness these resources to help avail themselves of the more limited services available in the area. Moreover, elements of the intervention designed to build motivation and self-efficacy might end up reducing these in the longer term, if after being heightened by the intervention, the system proves to be unavailable to them. Since evaluation of potential harms may require a longer follow-up period and larger samples, these are often beyond

the scope of the original design and research commission, although dark logic models can still be applied retrospectively to evaluate intervention effects.<sup>33</sup> Meta-analysis across several studies and contexts would also be useful as the research field unfolds, although unintended harms may not be apparent in primary studies, a synthesis across the different contexts in which the intervention has been applied can be informative.

Finally, while it is difficult, but not impossible to disentangle the process of designing complex interventions in order to provide some transparency and rigour to the process, the very nature of complex interventions, means that it is hard to fully reduce its components to individual parts. Rather, when the intervention is applied in different contexts, active ingredients/key functions start to be able to be identified after observing how the intervention functions across different contexts—and so perhaps it would be best to talk about identifying 'emergent properties' over a longer time frame.<sup>34</sup> This is an ongoing process where both the intervention and what happens when it is applied in a context, are under examination, since 'intervention effects can be modulated (attenuated or amplified) by the characteristics and dynamic evolution of the system (context) in which it is implemented'.<sup>34</sup> The context is not just the backdrop against which the intervention takes place, but a 'fuzzy boundary' between the context and the intervention exists.<sup>34</sup> While this is recognized right from outset of the design process by incorporating user perspectives and developing an understanding of the context, as illustrated in the process described in this article—this emphasis should continue to feature as the research progresses towards trial and implementation phases too.

#### AUTHOR CONTRIBUTIONS

Harris conceived the study, led the design and interpretation of data, contributed to qualitative data acquisition and drafted the article. Lowers contributed to qualitative data collection, interpretation of data and critically revised the article. Van Der Zande led the qualitative data collection, contributed to interpretation of data and critically revised the article. Stanley contributed to the qualitative data collection and critically revised the article. Cooke contributed to theory phase of the study, the development of the goal setting aspect of the intervention and critically revised the article. All authors gave their final approval and agreed to be accountable for all aspects of the work.

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## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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