Title:

Self help materials for smoking relapse prevention: A process evaluation of the SHARPISH randomised controlled trial

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ABSTRACT:

Background: UK Stop Smoking Services are effective at assisting smokers to quit. However, smoking relapse rates are high, representing a significant public health problem. No effective interventions are currently available. This embedded qualitative process evaluation, within a randomised controlled trial of a self-help smoking relapse prevention intervention, aimed to understand patient perspectives in explaining the null trial finding, and to make recommendations for intervention development.

Methods: The intervention was a British version of the 'Forever Free' self help booklets (SHARPISH - ISRCTN 36980856). The qualitative evaluation purposefully sampled 43 interview participants, triangulated with the views of 10 participants and 12 health professionals in focus groups. Data were thematically analysed.

Results: Analysis revealed important variation in individual engagement with the self help booklets. Variation was interpreted by the meta-themes of 'motivation for cessation', and 'positioning on information provision', interacting with the theme of 'mechanisms for information provision'.

Conclusions: Targeting self help information towards those most motivated to engage may be beneficial, considering the social and cultural realities of individual's lives. Individual preferences for the mechanisms of information delivery should be appraised when designing future interventions. Long term personalised follow up may be a simple step in improving smoking relapse rates.

Key words: Smoking, Public health, Research

INTRODUCTION

UK NHS Stop Smoking Services are effective and cost effective at helping motivated quitters to stop

smoking (1). Maintenance of long term smoking abstinence is extremely difficult for the ex-smoker, for

many possible psychological (e.g. stress), social and culturally based reasons (e.g. pleasure of smoking and a

social environment conducive to smoking) (2) Most short-term quitters will return to regular smoking –

approximately 75% of those who manage to quit for four weeks will return to smoking by 12 months (3).

A Cochrane review reported insufficient evidence to support the use of any specific intervention for

preventing smoking relapse (4), and there is no relapse prevention intervention recommended by NICE, who

suggest that further research is needed (5). Following an exploratory meta-analyses (6, 7), the Sharpish trial

(ISRCTN 36980856) sought to evaluate the effectiveness of self-help educational booklets, originally

developed in the USA for testing in unaided quitters (8). The intervention aimed to prevent smoking relapse

in the UK population of people who quit smoking after receiving intensive cessation treatment(9). The trial

found no statistically significant difference between groups on the primary or secondary outcomes(10),

although found an overall increased rate of long term smoking abstinence in comparison to the general

population of quitters accessing stop smoking services(11). This study sought to evaluate patient

perspectives that might offer insight into the observed trial findings.

Process evaluation of randomised controlled trials involving qualitative methods is increasingly recognised

as important in informing and assisting with interpretation of trial outcomes (12, 13),(14). Process

evaluation enables a view inside the 'black box' of complex interventions – the human use, experience and

views on the intervention (14). UK Medical Research Council guidance recommends conducting process

evaluation studies in order to explain unexpected outcomes, understand contextual factors, and aid

implementation (15), thus process evaluation should be integral to the design of randomised controlled

trials (16). To the best of our knowledge, there is no published qualitative process evaluation reporting on smoking relapse prevention interventions.

METHODS

The Sharpish Trial (ISRCTN 36980856) recruited short-term quitters (quit smoking for 4 weeks) from NHS stop smoking clinics (10,9). Following randomisation, self-help educational materials were posted to participants. 1,407 carbon monoxide (CO) validated quitters were randomised. Intervention group participants (n=703) received a set of eight revised 'Forever Free' booklets, and control group participants (n=704) received a single leaflet, currently given to NHS patients. The primary trial outcome was prolonged, CO-verified abstinence from months four to 12 with no more than five lapses. At 12 month follow up qualitative data were collected.

The qualitative process evaluation interviewed participants who had and had not relapsed in the control and intervention arms, between June 2013 and June 2014. Following this, we also undertook iterative focus groups with trial participants, and group discussions with a selected sample of smoking cessation professionals, to triangulate and verify analysis.

Ethical approval for the study was obtained from the East of England Research Ethics Committee (11/EE/0091). All individuals who took part in interviews or focus groups, gave written consent. We reimbursed participants with travel expenses and a £20 shopping voucher.

For the interviews, a purposive sample of 43 participants recruited to the SHARPISH trial was selected. Sampling aimed to achieve maximum variation across demographics of trial participants (Table 1). The sample was representative of the trial study population in terms of including gender, employment, use of

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pharmacological interventions, service attendance and area of recruitment (Table 2). We purposefully over-sampled those who reported continued abstinence at follow up since this was the primary trial outcome. Of the 43 interviews, 23 participants were recruited from the trial intervention group and were specifically probed during interviews around their use of the self help booklets. 20 control group participants were asked about their experiences of attempting to stay stopped from smoking, or gave detailed descriptions of their relapse experiences. Non-participation rates for interviews were approximately 20%. The main stated reason for non-participation was a lack of time. The interview guide was developed in consultation with lay representatives, to elicit narratives of smoking cessation and continued abstinence or relapse, before understanding the extent to which participants engaged with the self help information *(interview guide as supporting information).* Interviews were audio recorded and transcribed and detailed researcher notes commented on social context, as interviews were mainly conducted in interviewees own homes.

We purposefully recruited a further sub-sample of trial participants to triangulate the data and iteratively develop and verify our initial analysis in focus groups. Demographically focus group participants were broadly similar to trial participants for all parameters with the exception of younger participants (18–29) who were not represented (see Table 3). Finally we selectively sampled professionals to take part in a group discussion. The group was undertaken with core service staff (specialist advisors based at stop smoking clinics) who recruited 73% of the participants to the trial.

A thematic content analysis (17) approach was used to code data in transcripts that was relevant to exploring use of the self help booklets. Coding continued until saturation of themes was reached. NVivo (v10) software was used to assist with the analysis. Initial open coding was organised into higher level coding, and interpretations reported here are made on the basis of this. Coding was undertaken by CN. Two independent researchers (BK and TB) undertook independent coding on 25% of the transcripts. Coding was discussed at analysis team meetings attended by BK, TB and CN, until consensus was reached, and also at

study steering groups attended by the trial team and a service user representative. Final analysis was discussed at focus/discussion groups and with lay representatives for verification.

RESULTS:

Analysis revealed important variation in individual engagement with the self help booklets. Variation was interpreted by the meta-themes of 'motivation for cessation', and 'positioning on information provision', interacting with the theme of 'mechanisms for information provision'. A further meta-theme, 'identity' will be separately reported elsewhere.

Motivation for cessation

A wide variety of motivations for cessation were retrospectively discussed. Those clearly demonstrating an expressed 'internal' motivation (to stop smoking 'for themselves') seemed to engage more with the self help information supporting continued cessation (abstinence). There were positive comments specifically mentioning information given on the *physiology of stopping smoking* and the *physical process of craving*.

There was one bit that I did read which I found quite interesting was the effects when you stop smoking…what happens after one day…two days, after a week… and then sense, taste and smell, starts to improve…and then it gets to the point of uh your chances of a heart attack become the same as a non-smoker…and after so long, you know, and that's a target to go for

(Participant number 0766: male, aged 54, abstinent, intervention group)

Participants internally motivated for smoking cessation valued scientific information that reaffirmed their initial reasons for stopping smoking, and provided motivation to maintain abstinence for a certain period of

time (e.g. to reach the point at which chances of a heart attack become the same as a non-smoker). Others commented specifically on practical content of the booklets that they felt able to implement themselves, such as the suggestions for distraction strategies:

If you, you start getting the urge then to try and keep yourself, erm, keep your, your mind occupied and, and (coughs) and so to divert it away from, erm, from just thinking about cigarettes …the drinking plenty of, something I never used to do, drink plenty of water

(Participant number 0677: male, aged 75, relapsed, intervention group)

Similarly, some participants reported referring back to the booklets to reaffirm their motivation to stay abstinent, and to self-praise by reminding themselves of how long it had been since the initial quit attempt:

But then obviously I went back to them, and then obviously…yes I already had it open because, yes I did, cos every now and then I would I'd just look at it just to remind myself that, you know, now you know where I am now, where I was even like six months ago…

(Participant number 0723: female, aged 45, abstinent, intervention group)

Those attending the focus groups felt that key to maintaining abstinence was an initial internal motivation for cessation, and an ongoing commitment to this - a real drive to want to succeed. The consensus was that no booklet or leaflet would be sufficient to prevent relapse if internal motivation to stay quit was not sufficiently strong. However, once quit, and with a strong desire to stay quit, participants did report that it was useful to be able to refer to information about the benefits of staying abstinent from smoking.

Positioning on information provision

Many participants took a position that suggested they saw the self help information as a threat to their individual autonomy, condescending, or implying a lack of education. For example, some participants expressed that the booklets were *overly simplistic*, or contained *too much information*. Others defended their position by projecting the threat to their autonomy onto the booklets - reporting that they felt that the booklets contained *nothing that I didn't know already*:

What was in the booklets is… it was more geared up to somebody that, but then I still think that people who are smoking know all of the coping strategies to get through it and things, maybe it just reiterates it a bit more, but… it was teaching your granny to suck eggs

(Participant number 0748: female, aged 39, abstinent, intervention group)

This point was specifically mentioned in the context of the advice that had already been received via the stop smoking service:

Most - as I said I'd already received from (name), or from my advisor

(Participant number 0702: male, aged 33, relapsed, intervention group)

Some participants reported *flicking through the booklets*, *not reading all the booklets* or reading them once, but *never referring back* to them, suggesting resistance and distancing:

yeah I was given the booklets, yeah I read through most of them but ummm, yeah, and then they were put out of the way, and I haven't looked at 'em since, to be honest! (laughs)

(Participant number 0638: male, aged 59, abstinent, intervention group)

The humour and pseudo confession ('to be honest') presented here provide evidence of underlying cultural assumptions about the paternalistic bias that is perceived by recipients of health information, and how this may be interpreted as a threat to individual autonomy. For this man, positioning himself as impervious to the messages contained in the booklets, the information was perceived as irrelevant, threatening his sense of self esteem and individual autonomy to 'choose' to remain abstinent of his own free will.

Mechanisms for the provision of information

Suggestions were given for possible ways in which the self help booklets might be improved, such as abbreviated versions and targeting content towards certain age groups. Frequent suggestions were for electronic versions of the self help booklets, in PDF format, as an 'app', or as web based support. In the context of the null finding of the SHARPISH trial, there are strong grounds for suggesting that the mechanism for delivery of the information requires adaptation in order to ensure that information is delivered in a way that is sensitive to the contexts of individual's lives. Particularly, portability and ease of access were mentioned:

Most people now…have either got a computer or a tablet, or if they could be downloaded onto kindle, I mean, I would certainly be in favour of that, because it goes everywhere with me

Participant number: 0728 , female, aged 49, abstinent, intervention group

However, the importance of face to face support as a mechanism of action was emphasised. Participants reported increased motivation due to regular initial meetings with stop smoking advisors, and a sense of reward when they managed to maintain the quit and had this validated via a CO test with the stop smoking advisor. There was a feeling that self help support could be a useful adjunct to the advice received by appointments with stop smoking advisors, but that the one to one support, combined with the

pharmacological support, was the key element to a long term successful quit attempt. Focus group participants corroborated the interview data, explaining that they enjoyed the extended contact with the research team and the follow up CO test at 12 months. They suggested that continued contact could be an addition to the stop smoking service, encouraging maintenance of a long term quit.

Similarly in our focus groups with stop smoking professionals, it was suggested that improved relapse rates across trial groups could be due to the follow up provided by the research team and advisors raising the subject of relapse with participants as part of the recruitment process. As a practical implication of this possibility, professionals suggested that the service could consider providing patients with a contract for longer term support to help encourage continued abstinence from smoking, or to encourage relapsed smokers to return to the service.

DISCUSSION

Main finding of this study

The quantitative findings from the trial (11) in which this process evaluation was embedded concluded that the theory based self help information booklets had no overall effect on long term smoking relapse rates. The findings of the qualitative process evaluation clearly show a mixed response to the self help booklets. It is therefore possible to interpret the null trial finding by viewing self help information for smoking relapse prevention as rejected by individuals as, overall, irrelevant to the social and cultural contexts of their lives.

What is already known on this topic

For participants who reported an internal motivation to stop smoking, the motivation appeared to drive engagement with the self help approach, suggesting that targeting self help materials towards those with clear internal motivation may be appropriate. However, motivation for smoking cessation is complex and

individually negotiated, situated in a wider social and cultural context, such as the family and social groups with which individuals are engaged with on a daily basis. Indeed, viewing smoking less as a 'health behaviour' and more as a 'health practice' (18) that is understood in a wider context alongside other social practices, such as drinking alcohol and socialising, suggests that abstaining from smoking is a complex behavioural and social phenomena that requires more than motivation and support for abstinence, but an understanding of health behaviour as 'emergent and contingent'(19).

Under the meta-theme of 'positioning on information provision', participants were seen to negatively orientate their responses to the booklets, suggesting that they did not offer any particularly new or novel insights. This may in part be due to the detailed advice that had already been received via stop smoking advisors, but was also interpreted as an attempt to morally defend behaviour, and strengthen individual autonomy to quit without the need for support, in the face of what was perceived as a paternalistic approach to information giving. Therefore developing interventions that fit with people's everyday lives and world views, their conceptualisation of autonomy, is critical, as opposed to attempting to 'fit' the subjective realities of people's lives into a dominant clinical (bio-medical) worldview of educational approaches to health information provision

Our findings emphasise the importance of human face to face contact. Recent advances in our understanding of health communication suggest that written information should be adjunct to, and not replace, face to face advice giving. Many people may not read frequently, or have poor literacy skills, and this should be considered when targeting written self help information. In related fields, for example mental health self-help, it is well recognised that self help materials should be assessed for readability, cultural appropriateness and accessibility (20).

What this study adds

Careful targeting of self-help materials for smoking relapse prevention may be a way forward, as resources are wasted on those who see self help information as irrelevant to their individual contexts. An assessment to determine internal/external motivation of initial cessation would be a positive step, targeting the self-help approach towards those demonstrating an internal motivation to quit. Understanding participant preferences for the mechanisms of intervention delivery, would also assist with tailoring long term smoking relapse prevention approaches, which may impact on the effectiveness of newly developed interventions.

Process evaluation of complex interventions, particularly in the field of smoking relapse prevention where there remains a need to identify effective interventions, is critical to assist researchers with developing and evaluating new approaches. In the SHARPISH trial, the process data offer an explanatory context for the trial null result by suggesting that the self help approach was only accepted and agreeable to some individuals. Others defended their position of autonomy, by rejecting the notion of self help information. In the UK context of specialist smoking cessation services from which the SHARPISH trial recruited, the self help booklets studied did not appear to offer insights and assistance to individuals above and beyond the intensive cessation support they had already received. This is in contrast to studies with *unaided* quitters who did not receive specialist cessation support, where positive findings were observed for self help relapse prevention behavioural interventions (21).

Participants from both trial groups reported feeling motivated to continue to remain smoke free knowing that they would be contacted by a researcher, suggesting that personal contact mechanisms are often preferred by participants. Within the context of the SHARPISH trial it is conceivable that the personalised face-to-face follow-up trial assessment (explaining high trial follow up rates(10)), had a therapeutic effect on outcome across both trial groups. This suggests that future relapse prevention interventions should consider incorporating long term personalised follow up of participants following a quit attempt. Mechanisms for delivering this contact should be tailored to fit with individual preferences, by, for example, utilising social media and online contact, but also acknowledging the importance of face to face contact.

Limitations of this study

This was a relatively small qualitative process evaluation study. Despite purposive sampling we may not have captured the full range of possible participant perspectives on the self help intervention. It is also possible that interview participants were influenced by respondent bias.

COMPETING INTERESTS

None declared

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Table I: Summary sample frame of key sampling characteristics:

Smoking status	Intervention	control
abstinent	15	11
relapsed	8	9

Table II: Study A - Participant Characteristics (secondary sampling criteria)

Trial code	Smoking Status (A = *abstinent, R = relapsed*)	Intervention group (I = Intervention; C = Control)	Age	Gender (m= male; f= female)	Employment status	Nicotine dependence: *baseline cigs per day*	Smoking history: *No. of prior quit attempts*	Use of pharmacological intervention (NRT = Nicotine replacement therapy)	Service attendance (SSA = Stop Smoking Advisor, GP = General Practice)	Area
638	A	I	54	m	employed	28	1	NRT	SSA at GP	Norfolk
677	R	I	75	m	retired	20	2	champix	SSA at GP	Norfolk
671	A	I	75	m	retired	20	1	NRT	SSA at GP	Norfolk
673	A	C	71	f	retired	20	missing	NRT & electronic cigarettes	SSA at hospital	Norfolk
727	A	C	53	f	employed	20	2	NRT	SSA at GP	Norfolk
664	A	C	37	m	self employed	30	1	champix	SSA at GP	Norfolk
672	A	C	42	m	employed	20	1	NRT	SSA at GP	Norfolk
684	R	C	47	m	employed	42	2	champix	SSA at hospital	Norfolk
713	A	I	73	m	retired	15	6	champix	SSA at leisure centre	Norfolk
666	A	I	65	m	retired	10	1	champix	SSA atGP	Norfolk
708	A	I	63	m	employed	40	1	champix	SSA at GP	Norfolk
702	R	I	33	m	self employed	25	0	none	SSA at hospital	Norfolk
728	A	I	49	f	employed	10 - 15	1	NRT	SSA at GP	Norfolk
717	A	C	42	m	employed	17.5	1	champix	SSA at GP	Norfolk
729	A	C	42	m	employed	14	1	champix	SSA at GP	Norfolk
779	R	C	44	f	unemployed	20	12.5	champix	SSA at GP	Suffolk
720	A	I	69	m	retired	20	2	champix	SSA at GP	Norfolk
777	R	I	59	m	employed	20	1	champix	SSA at GP	Norfolk
757	R	I	69	m	self employed	11	3	NRT	SSA at GP	Norfolk
761	A	I	44	m	employed	15-20	2	champix	SSA at hospital	Norfolk

674	R	I	49	f	carer	20	3	champix	SSA at hospital	Norfolk
723	A	I	45	f	looking after home	10	5	champix	SSA at GP	Norfolk
740	R	C	62	m	other	14	5	NRT	SSA at GP	Norfolk
800	R	I	45	m	employed	20	2	NRT	SSA at GP	Norfolk
697	R	C	46	f	employed	10	5	champix	SSA at GP	Norfolk
754	R	C	45	f	employed	15	3	champix	SSA at hospital	Norfolk
766	A	I	54	m	employed	10 - <20	1	champix	SSA at GP	Norfolk
748	A	I	39	f	employed	20	3	champix	SSA at hospital	Norfolk
784	A	C	44	f	self employed	20	4	NRT	ssa at GP	Suffolk
796	A	C	38	f	employed	20	1	champix	SSA at GP	Norfolk
803	A	C	48	f	employed	5	8	champix	SSA at GP	Norfolk
860	A	C	55	f	employed	10	3	NRT	SSA at hospital	Norfolk
792	R	C	50	f	employed	20	multiple	champix	ssa at GP	Norfolk
826	R	C	64	f	retired	10	3	NRT	ssa at GP	Norfolk
818	A	I	37	f	looking after home	10	1	champix	ssa at GP	Norfolk
862	A	I	25	f	self employed	3	1		ssa at gp	Norfolk
940	A	I	56	f	employed	20	10	champix	ssa at GP	Herts
891	A	C	27	m	employed	15	12	champix	ssa at GP	Norfolk
937	A	C	59	f	unsure	7.5	multiple	NRT	ssa at GP	Herts
1164	A	C	68	f	retired	17.5	15	NRT	SSA at community centre	Lincolshire
760	R	I	64	f	retired	5	8	champix	SSA at hospital	Norfolk
786	A	I	58	f	employed	20	3	NRT	SSA at hospital	Norfolk

Table III: Study B – Focus group participant characteristics

Sharpish Trial participant code	Gender (m= male; f = female)	Employment Status	Nicotine dependence: baseline cigs per day	Smoking history: No. of prior quit attempts	Intervention Group (I = Intervention; C = Control)	Service attendance (Core service = Stop smoking service)
0203	m	Retired	20	3	I	Core Service
0255	m	employed	17.5	1	C	Core Service
0364	m	employed	10	5	I	Core Service
0669	m	Retired	7	1	C	Core Service
0720	m	Retired	20		I	Core Service
0766	m	employed	20	1	I	Core Service
0786	f	employed	20	3	I	Core Service
0792	f	employed	20		C	Core Service
0803	f	employed	8	3	C	GP Practice
0809	f	employed	17.5	10	C	Core Service
0880	f	Retired	20	3	I	GP Practice