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**Treatment manuals, training and successful
provision of stop smoking behavioural support**

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ABSTRACT

Objective: Translating evidence-based behaviour change interventions into practice is aided by use of treatment manuals specifying the recommended content and format of interventions, and evidence-based training. This study examined whether outcomes of stop smoking behavioural support differed with practitioner's use and evaluation of treatment manuals, or practitioner's training.

Methods: English stop smoking practitioners were invited to complete an online survey including questions on: practitioners' training, availability, use and perceived utility of manuals, and annual biochemically-validated success rates of quit attempts supported (practitioner-reported). Mean success rates were compared between practitioners with/without access to manuals, those using /not using manuals, perceived utility ratings of manuals, and consecutive levels of training completed.

Results: Success rates were higher if practitioners had a manual (Mean (SD)=54.0 (24.0) versus 48.0 (25.3), $t(838)=2.48$, $p=.013$; $n=840$), used a manual ($F(2,8237)=4.78$, $p=.009$, $n=840$), perceived manuals as more useful ($F(3,834)=2.90$, $p=.034$, $n=840$), and had completed training ($F(3,709)=4.81$, $p=.002$, $n=713$). Differences were diminished when adjusting for professional and demographic characteristics and no longer reached statistical significance using a conventional alpha for perceived utility of manuals and training status (both $p=0.1$).

Conclusions: Practitioners' performance in supporting smokers to quit varied with availability and use of treatment manuals. Evidence was weaker for perceived utility of manuals and practitioners' evidence-based training. Ensuring practitioners have access to treatment manuals within their service, promoting manual use, and training practitioners to competently apply manuals is likely to contribute to higher success rates in clinical practice.

Keywords: smoking cessation, implementation, manuals, professional education, knowledge translation

INTRODUCTION

There has been a growing investment in developing and evaluating interventions to change health-related behaviours (Michie, van Stralen, and West 2011). Evaluations of such interventions have the potential to promote more effective, efficient and safer patient care and improve health outcomes (Foy et al. 2007; Grimshaw et al. 2006). In order for effective behavioural interventions to achieve desired health benefits in clinical practice, interventions must be adopted and implemented consistently by healthcare professionals, systems and organisations (Eccles et al. 2009; Penney and Foy 2007). However, the translation of evidence into practice is typically a slow, haphazard process embedded in a complex system of interactions between researchers, policy makers, and healthcare managers and professionals (Grimshaw et al. 2001). This is particularly true for health behaviour change interventions, which are typically complex, in that they consist of multiple, potentially interacting components, are often context-dependent and delivered by multiple healthcare professionals to a range of recipients (Bonell et al. 2012; Grol and Grimshaw 2003; Michie et al. 2009). It is thus often challenging to ensure the achievement of standards and consistency in their implementation (Alexander and Hearld 2012). Consequently, it is unsurprising that complex behavioural interventions with demonstrated effectiveness often achieve variable and modest effects when implemented in wider clinical practice (Chilvers et al. 2002).

Providing behavioural support and medication for smoking cessation is a complex and highly cost-effective, life-preserving intervention (National Institute for Clinical Excellence 2008). Behavioural support interventions consist of advice, discussion and targeted activities aimed to minimise a smoker's motivation to smoke, maximise resolve not to smoke, to help with strategies to minimise exposure to smoking cues, cope with urges when they occur, and make the best use of adjunctive activities, such as smoking cessation medications (West et al. 2010). In the UK, behavioural support interventions have been widely implemented via a network of National Health Service (NHS) stop smoking services, which support smokers making attempts through medication provision and weekly one-to-one or group behavioural support sessions. Smokers engaging with these services are approximately four times more likely to quit than those quitting without support (Ferguson et al. 2005). These services aim to provide evidence-based support based on guidelines outlining the recommended content and format of smoking cessation behavioural support (Department of Health 2012). However, the outcomes across these services are highly heterogeneous; in 2013/14, four-week carbon monoxide validated quit rates ranged from 3% to 66% (The Health and Social Care Information Centre 2014).

Methods are needed to promote the consistent and systematic uptake of research findings into routine clinical practice (Eccles et al. 2009). One potential method is 'treatment manuals,' which typically refer to: structured, procedural texts outlining the rationale, goals and recommended content of an intervention (Wilson 1996). Use of manuals in clinical practice has the potential to increase implementation by aiding replication, facilitating training and supervision, promoting consistency and helping focus and shape the content of typically time-limited interventions (Wallace and von Ranson 2011; Wilson 1996). If the content of manuals is informed by systematic reviews of evidence or evidence-based clinical guidelines,

manuals can provide a platform for translating the content of interventions with demonstrated effectiveness into clinical practice (Wilson 1996).

Treatment manuals are available in a number of UK stop smoking services (West et al. 2010). However, it has been argued that such manuals may not be currently used routinely in practice, as stop smoking practitioners operating under the same treatment manual have widely varying success rates (Brose, McEwen, and West 2012a). It has also been demonstrated that fidelity to treatment manuals is typically low in the services, with an average of approximately 50% of manual-specified content being routinely delivered in clinical practice (Lorenatto et al. 2014; Lorenatto et al. 2013). These findings raise the question of the extent to which stop smoking practitioners actually use treatment manuals in clinical practice. Surveys in the wider cognitive behavioural therapy literature identify low rates of self-reported use of treatment manuals amongst clinicians, and highlight clinician's education, years of experience, and attitudes towards treatment manuals as influencing factors (Addis and Krasnow 2000; Barry et al. 2008; Simmons et al. 2008; Tobin 2007; Wallace and von Ranson 2011). The extent to which such factors influence stop smoking practitioners' use of manuals remains unclear. Furthermore, critics of manual-based therapeutic approaches argue manuals can in fact be detrimental to treatment outcomes by restricting therapists' flexibility in the delivery of interventions and impairing the therapist-patient interaction (Wilson, 1996). To our knowledge, the extent to which treatment manual use is associated with improved or reduced success of behavioural support provided to smokers has also not been examined.

Training is an additional method to support the translation of evidence into clinical practice. There is a trend towards specifying the competences (i.e. core knowledge and skills) required by healthcare providers to deliver effective care, including an evidence-based framework of competences for delivering health behaviour interventions (Dixon and Johnston 2010) and cognitive behavioural therapy (Roth and Pilling 2008). This is part of a general call for evidence-based competences to feature in certification, training and continuing professional development for healthcare professionals (Muse and McManus 2013). A set of competences for delivering smoking cessation behavioural support has been identified (Michie, Churchill, and West 2011) and has informed the development of a national, evidence-based training program (www.ncsct.co.uk) in the UK. A knowledge certificate can be achieved by accessing an online knowledge training programme and passing the related assessment. Those having passed the knowledge component can go on to complete a skills assessment. This programme is supplemented by face-to-face group courses in behavioural support. This training has been shown to increase stop smoking practitioners' knowledge and lead to a sustained increase in confidence in competence to deliver effective interventions (Brose et al. 2012b; Brose et al. 2012c). An association of training and service-level success has been found (Brose et al. 2014); however, the association of training with individual practitioners' success rates has not yet been evaluated.

This study therefore aimed to address the following research questions in the context of smoking cessation behavioural support delivered by the NHS Stop Smoking Services:

1. To what extent do stop smoking practitioners have access to and report using treatment manuals?
2. How useful do stop smoking practitioners perceive manuals to be?
3. Do outcomes of the support provided (i.e. successful quit rates) differ according to a) the availability; b) evaluation or c) use of treatment manuals; and d) level of training completed? Outcomes were anticipated to be better where treatment manuals were available, were evaluated as more useful, and were used, and for practitioners with at least some training.

METHODS

Study Design

All stop smoking practitioners contracted to work in the NHS Stop Smoking Services and registered between 2010 and 2012 with an online training programme (www.ncsct.co.uk) were invited via email to participate in an online survey. Additionally, those who had completed a similar survey in the previous year and were not registered for training were invited. A total of 8914 individual email invitations were sent (8534 based on registration information, 380 to additional previous respondents), about 10-15% were not deliverable and it is unknown what proportion of the remaining addresses were still active in this comparably transient workforce (Bauld et al. 2005). All managers of the 152 English NHS stop smoking services were also asked to forward the invitation to all practitioners in their service. The survey started with a filter question to establish whether responding practitioners were currently seeing smokers on behalf of a local stop smoking service. Reminder emails were sent one and two weeks after the initial invitation. The survey was closed after one month (December 2012). A prize draw for free registration, travel to and accommodation at a smoking cessation conference was used as an incentive; respondents wishing to be entered into the draw gave their name and contact details.

Measures

The survey included questions about the practitioners' demographic and professional characteristics, including age (18-25; 26-34; 35-44; 45-54; 55-64; 65 and over), years of experience, professional role (full-time 'specialist' practitioner or 'non-specialist' practitioner providing support as part of a wider role) and part of the job spent on smoking cessation (small part, main part, all of it). It also included questions to assess the availability of manuals, and practitioners' self-reported use and perceived utility of manuals (Table 1, Items 1-3). The content, phrasing and response options for these questions were informed by previous surveys of clinician manual use conducted in the context of clinical psychotherapy interventions (Barry et al. 2008; Tobin 2007; Wallace and von Ranson 2011).

Training status (Table 1) was derived from three separate yes/no questions (Have you registered with the NCSCT? Have you passed the NCSCT Stage 1 Assessment (knowledge)? Have you passed the NCSCT Stage 2 Assessment (skills)?).

Practitioners were also asked for their four-week, biochemically validated, successful quit rate in the last year. A quit attempt is deemed successful when, at a follow-up 4 weeks after a quit date, the client reports no smoking for the 2 weeks prior to the follow-up, and a carbon monoxide level of less than 10 parts per million is measured in expired air. The primary outcome measure for this study was the percentage of successful quits that the practitioner reported (i.e. 0 to 100%). Before giving their success rate, respondents were asked whether they knew the success rates of their clients; 47% said that success rates were fed back to them by their manager and 38% said they kept track of them, with only 16% saying they had no access to figures. They were asked to give an estimate. The survey also included questions related to other aspects of behavioural support delivered by practitioners that are not analysed in the present study (e.g. use and advice on electronic cigarettes (Beard et al. 2014) and water pipes, medications offered, practitioner's views on changes to the structure of public health in England, etc.)

Analysis

Mean success rates were compared across different responses for each question using t-test and ANOVAs, with significance levels set to 0.05. Some response options were collapsed to avoid small group sizes (Table 1).

In post-hoc analyses, success rates were compared across practitioners with different ages, gender, length of experience and roles. Main analyses were repeated adjusting for variables showing a link with success rates.

RESULTS

Sample

Due to the method of recruitment, the number of participants invited and response rates could not be determined. The survey was accessed 2,420 times, 249 respondents (10.3%) did not currently see smokers on behalf of a stop smoking service and were therefore not eligible to complete the survey. An additional 95 did not respond to any questions. A total of 1518 practitioners completed questions on manual use and 1237 questions on training. Analyses were restricted to practitioners who saw at least 25 clients in the previous year to allow sufficiently reliable estimation of success rates. Therefore the remaining sample for analyses was 840 practitioners for the manual use questions, and 713 for the questions on training.

Most practitioners completing the manual-use related questions were women (704/840, 83.8%), with the largest group between 45 and 54 years of age (37%). Over half (55%) were specialist stop smoking practitioners, whilst the remaining provided stop smoking support alongside their main role as healthcare adviser (14.0%), nurse (11.7%) or other profession. Smoking cessation was a 'small part of the job' for 39.5% of practitioners, the 'main part of the job' for 21.2%, and 'all of the job' for 39.2%. For almost all specialists (95.3%), it was the main part or all of their job. On average, practitioners had been working in stop smoking services for 7 years and 10 months (94 months, SD=47.7 months, median 7 years, 2 months).

Availability, use and perceived utility of treatment manuals

The vast majority reported that their service had a treatment manual (85.6%). The largest group reported that they were flexible in how they applied the content of the manual to their practice (69.4%), followed by those who aimed to remain close to the content of the manual (30.3%). Nearly half of all practitioners rated manuals in general as very useful.(Table 1).

Completion of training

Two thirds had completed the training and passed both the knowledge and skills assessment; most of the remaining respondents had achieved knowledge certification (Table 1).

Differences in outcomes

Success rates were higher for specialist practitioners (M (SD)=57.4 (22.6) than for non-specialists (M; SD)=47.9; 25.2, $t(768.1)=5.68$, $p<0.001$). They were also higher for male practitioners (M; SD=57.0; 23.5) than for female practitioners (M=52.4; 24.4, $t(839)=2.05$, $p=0.04$). This was confounded with role; among male practitioners, 65% worked as specialists, compared with 53% among female practitioners. Success rates did not differ with age ($F(5,834)=0.37$, $p=0.87$) or correlate with length of experience ($r=0.03$, $p=0.32$)

Success rates were higher for practitioners who knew that their service had a manual compared with those working at services without a manual, or who did not know whether a manual existed (Table 1). Success rates also differed according to use of manual (Table 1), practitioners who did not have or use a manual reported lower success rates than those who used a manual either flexibly ($p=.011$) or those who reported sticking closely to the manual ($p=.021$), other group differences were not significant. Success rates increased with practitioners' ratings of the usefulness of manuals, although individual group differences did not reach significance (Table 1).

Finally, success rates differed with practitioners' level of training (Table 1); in particular, those not registered for training reported lower success rates than those who had achieved the knowledge certificate ($p=.013$) or the knowledge and skills certificate ($p=.003$); differences between other groups did not reach significance.

When post-hoc adjusting for role and gender, differences were smaller for all comparisons and no longer reached statistical significance using a conventional alpha ($p<0.05$) for usefulness of manual and training status (Availability of manuals: $F(1, 836)=4.49$, $p=0.03$; use of manuals: $F(2, 835)=3.22$, $p=0.04$; perceived utility of manuals: $F(3, 832)=1.91$, $p=0.13$; training: $F(3, 707)=1.95$, $p=0.12$).

DISCUSSION & CONCLUSION

Discussion

In this survey of stop smoking practitioners in the English NHS stop smoking services, higher biochemically validated success rates were found if treatment manuals were available and used. Differences in success rates linked to perceived utility and training were smaller. These findings suggest that the availability and use of treatment manuals may help improve the translation of evidence into practice to achieve target outcomes. Although the evidence for an effect was weaker, perceived utility and evidence-based training may help improve performance in clinical practice.

The majority of practitioners reported that they were flexible in how they applied the content of treatment manuals in practice. This is consistent with findings from the wider cognitive behavioural literature (Tobin 2007) and with findings that stop smoking practitioners have low fidelity to treatment manuals, and deliver a high proportion of non-manual specified behavior change techniques (Lorenцatto et al. 2014; Lorenцatto et al. 2013). It has been argued that treatment manuals may limit flexibility during delivery of interventions and neglect the importance of therapist's clinical judgment (Wilson 1996), and that strict adherence may be detrimental to a therapeutic interaction, as not all content specified in manuals will be relevant to all of the individual needs of each intervention recipient (Kendall et al. 2008; Leventhal and Friedman 2004). The practitioners' reported flexible application of treatment manuals in practice may therefore reflect their tailoring of behavioral support to the specific client's needs.

The predominantly flexible application of treatment manuals also brings to light the question to what extent current treatment manuals are fit for purpose. This study did not assess to what extent manuals were evidence-based, comprehensible or written in an accessible way - all of which are likely to affect practitioners' evaluation and use of manuals. If treatment manuals were unrealistic or inappropriate (Lorenцatto et al. 2014), it would be unsurprising that practitioners adapt or flexibly apply manuals in practice. For instance, recommendations outlined in the treatment manual of a national telephone quitline service have been shown to be extremely comprehensive, expecting practitioners to deliver up to 28 unique behaviour change techniques per session (Lorenцatto et al. 2014). An average behavioural support session in this quitline service lasts approximately 13 minutes (Lorenцatto et al. 2014). If practitioners within this service were strictly adherent to the service's manual they would be required to deliver approximately 2 techniques per minute. Delivering such a high volume of BCTs in clinical practice may not be feasible or relevant to all clients, and may even be detrimental to the therapeutic relationship (Lorenцatto et al. 2014). It is thus important to consider the appropriateness, feasibility and usability of treatment manuals in order for their recommendations to be implemented consistently and effectively in practice.

Similarly, the present data also suggest that practitioners may be able to adequately judge when to adapt recommendations, as those reporting a flexible use of manuals reported similar success rates to those following them closely, and both were more successful than those who had no manual or reported not using one. Such findings could be interpreted in the context of the wider fidelity debate regarding whether strict, 100% fidelity of intervention delivery is a desirable, necessary, or even appropriate aim in clinical practice (Borrelli, 2011). The present findings contribute some preliminary support in favour of a more 'middle-ground' approach

to fidelity, in which core, prescribed intervention components are delivered with fidelity to manual, alongside a permissible degree of flexibility and tailoring in the delivery of non-essential intervention components (Borrelli 2011; Collins et al. 2009; Kendall et al. 2008). In the present study, such a flexible approach does not appear to compromise outcomes, and represents a potentially more feasible and realistic model of treatment delivery in clinical practice. Nonetheless, such findings may also result from alternative factors, in that practitioners with lower success rates may be working for under-resourced services that provide less training and access to manuals. Alternatively, practitioners' lower success rates may result from non-service level factors, such as delivering support to more socioeconomically disadvantaged or nicotine dependent smokers; both of which are factors associated with lower cessation rates in England (Ferguson et al. 2005).

Any relationship between training and practice may not be unidirectional, as the training generally was not compulsory (although strongly recommended by the English Department of Health), and more successful practitioners may be more motivated to continue their professional development. Also, while practitioners with certificates performed better than those not registered for training, achieving the knowledge certificate or both certificates showed no additional benefit over registration only. However, it appears likely that using the training programme, rather than achieving the certificates, is important to improving practice. We have previously found that time spent on the training was associated with improvements in knowledge (Brose et al. 2012b); the certification process may not fully reflect use of the training and any improvement in knowledge.

Limitations to the present study are that no information was available on the extent to which the sample was representative for all practitioners in England, as no data are available on the number or characteristics of practitioners working presently in the country. However, recruitment from a very widely used training was supplemented by recruitment of a substantial proportion not involved with the training to achieve a good representation of practitioners. The analysis also relied on self-report. There is evidence that stop smoking practitioners over-report the extent to which they deliver behavior change techniques (Lorenzatto et al. 2014), and discrepancies between self-reported and actual practice have been documented more generally for physicians (Cabana et al. 1999; Jones et al. 1990). However, self-reported success rates have been shown to be reasonably valid (Brose et al. 2013).

Conclusion

In smoking cessation support, an example of a complex health behavior change intervention, availability and use of treatment manuals are positively related with practitioners' performance, which has implications for future training and professional development. Stop smoking services should endeavor to provide the best, evidence-based support to save more lives by helping a high proportion of their clients to quit smoking. Implications of the present findings include that services should ensure that evidence-based manuals are available, acceptable and used in clinical practice. Future research should aim to determine what specific manual characteristics contribute to them being perceived as useful, and to establish

what minimum level of fidelity is required, and what level of tailoring is permissible for best effectiveness. The weak effect of training and training elements (e.g. knowledge or skills) on success rates warrants further research using more objective measures.

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Competing interests

LSB and FL's posts were funded by the National Centre for Smoking Cessation and Training (NCSCT) when the survey was conducted. RW has undertaken research and consultancy for companies that develop and manufacture smoking cessation medications. He also has a share of a patent in a novel nicotine delivery device. AMcE undertakes research and consultancy and receives fees for speaking from companies that develop and manufacture smoking cessation medications (Pfizer, GSK and Novartis). He also has a share of a patent for a novel nicotine delivery device and he is the director of the NCSCT.

Author Contributions

FL and LB contributed to the conception and design of the study. FL, LB, AMC contributed to the acquisition of data. All authors contributed to data analysis and data interpretation. All authors contributed to drafts of the article and revised the article critically. All authors have approved the final article submitted.

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Table 1. Survey questions, responses and success rates

Question and response options	N (%)	Mean (SD) biochemically verified success rate
1. Availability of treatment manuals		
Does the Stop Smoking Service for which you work have any treatment manuals or guidance documents telling you how to structure and deliver one-to-one behavioural support? (n=840)		
a. Yes	719 (85.6)	53.96 (24.01)
b. No or don't know	121 (14.4)	48.07 (25.34)
Comparison of success rates		t(838)=2.48, p=.013
2. Use of treatment manuals		
Which statement best describes how you use (or don't use) treatment manuals or guidance documents when delivering one-to-one behavioural support? (n=840) ¹		
a. I try to stick closely to the recommended content and structure of behavioural support in my service's treatment manual.	248 (29.5)	54.77 (23.50)
b. I am flexible in how I apply the recommended content and structure of behavioural support in my service's treatment manual.	504 (60.0)	53.59 (24.30)
c. I don't usually follow the recommended content or structure of behavioural support in my service's treatment manual.	6 (0.7)	38.83 (20.82)
d. I have never seen or been given a treatment manual by my service.	82 (9.8)	46.24 (25.54)
Comparison of success rates		F(2,837)=4.78, p=.009
3. Perceived utility of treatment manuals		
In general, how useful can treatment manuals be for planning and delivering one-to-one behavioural support sessions? (n=838) ²		
a. Not at all useful	15 (1.8)	48.47 (24.64)
b. A little bit useful	86 (10.3)	48.60 (27.03)
c. Moderately useful	283 (33.8)	51.20 (23.94)
d. Very useful	376 (44.9)	55.02 (22.77)
e. Extremely useful	78 (9.3)	55.94 (28.05)
Comparison of success rates		F(3,834)=2.90, p=.034
4. Completion of training (n=713)		
a. Not registered	79 (11.1)	43.39 (24.83)
b. Registered, no certificate	30 (4.2)	50.07 (28.72)
c. Achieved knowledge certificate	134 (18.8)	54.40 (26.06)
d. Achieved knowledge and skills certificates	470 (65.9)	54.22 (22.82)
Comparison of success rates		F(3,709)=4.94, p=.002

Question numbers not as in actual survey

¹ Response options c and d collapsed for analysis, resulting in success rate for n=88 of M=45.74, SD=25.22.

² Response options a and b collapsed for analysis, resulting in success rate for n=101 of M=48.58, SD=26.57.

Highlights for the manuscript titled: *Association of treatment manuals and training with successful provision of stop smoking behavioural support*

- We examine the association between availability and use of treatment manuals, evidence-based training and successful quit outcomes
- Quit outcomes higher if practitioners had and used a treatment manual
- Quit outcomes higher if practitioners rated manuals as more useful
- Quit outcomes higher if practitioners had completed evidence-based training
- Findings highlight implications for future practitioner training and continuing professional development