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An Evaluation of the Effectiveness of Recruitment Methods: The Staying Well after Depression Randomized Controlled Trial

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Abstract

Background—Randomized controlled trials (RCTs) are widely accepted as being the most efficient way of investigating the efficacy of psychological therapies. However, researchers conducting RCTs commonly report difficulties recruiting an adequate sample within planned timescales. In an effort to overcome recruitment difficulties, researchers often are forced to expand their recruitment criteria or extend the recruitment phase, thus increasing costs and delaying publication of results. Research investigating the effectiveness of recruitment strategies is limited and trials often fail to report sufficient details about the recruitment sources and resources utilised.

Purpose—We examined the efficacy of strategies implemented during the Staying Well after Depression RCT in Oxford to recruit participants with a history of recurrent depression.

Methods—We describe eight recruitment methods utilised and two further sources not initiated by the research team and examine their efficacy in terms of (i) the return, including the number of potential participants who contacted the trial and the number who were randomized into the trial, (ii) cost-effectiveness, comprising direct financial cost and manpower for initial contacts and randomized participants, and (iii) comparison of sociodemographic characteristics of individuals recruited from different sources.

Results—Poster advertising, web-based advertising and mental health worker referrals were the cheapest methods per randomized participant; however, the ratio of randomized participants to initial contacts differed markedly per source. Advertising online, via posters and on a local radio station were the most cost-effective recruitment methods for soliciting participants who subsequently were randomized into the trial. Advertising across many sources (saturation) was found to be important.

Limitations—It may not be feasible to employ all the recruitment methods used in this trial to obtain participation from other populations, such as those currently unwell, or in other geographical locations.

Recruitment source was unavailable for participants who could not be reached after the initial contact. Thus, it is possible that the efficiency of certain methods of recruitment was poorer than estimated.

Efficacy and costs of other recruitment initiatives, such as providing travel expenses to the in-person eligibility assessment and making follow-up telephone calls to candidates who contacted the recruitment team but could not be screened promptly, were not analysed.

Conclusions—Website advertising resulted in the highest number of randomized participants and was the second cheapest method of recruiting. Future research should evaluate the effectiveness of recruitment strategies for other samples to contribute to a comprehensive base of knowledge for future RCTs.

Keywords

Recruitment; randomized controlled trial; RCT; methodology; cost effectiveness

Introduction

The randomized controlled trial (RCT) is widely regarded as the gold standard for investigating the efficacy of interventions, including psychological interventions. However, researchers conducting RCTs commonly report difficulties recruiting an adequate sample within planned timescales [1]. Failure to recruit a large enough sample of participants results in a reduction of statistical power and, if recruitment is biased towards certain sub-groups within the targeted population, limits the generalizability of findings. As a consequence, failure to recruit frequently results in RCTs unable to answer the research question addressed [2] or substantial extra cost to recruit a large enough sample [3]. The Medical Research Council guidelines on developing and evaluating complex interventions [4] highlight the critical importance of feasibility work, which can evaluate recruitment potential for a trial and assist the refinement of recruitment methods. In some cases up-scaling of recruitment from a small-scale to large-scale trial introduces unforeseen problems. It is therefore valuable to understand why recruitment fails and to learn from the experiences of large trials.

Many reasons are posited as to why recruitment for RCTs is problematic. First, overestimation of eligible candidates by researchers can result in a lack of an appropriate recruitment plan and an extension of the recruitment phase prolongs the trial [5]. Second, participant-related factors, such as ill-health, age or gender may introduce recruitment difficulties. For example, elderly participants may be less likely to participate in trials because they may be less able to attend appointments if they are physically frail; those of a lower economic status and young men may be less likely to seek help for mental health issues [5, 6]. Third, environment-related factors, such as how the media is

portraying the research topic, may result in distrust of specific research and unwillingness to participate [5]. Similarly, economic instability may affect potential participants' willingness and ability to engage in trials. Fourth, RCTs are designed to allocate participants randomly to trial arms, some of which may be less desirable to the potential participants [5]. For example, some participants may receive their preferred treatment whilst others may receive no treatment at all. Finally, recruitment of specific samples, such as those with a mental illness, can be problematic because people may decline to participate due to feeling stigmatised [6].

In an effort to overcome recruitment difficulties, researchers often expand their recruitment criteria or extend the recruitment phase, thus increasing costs and delaying publication of results [3, 5, 7]. They also may adopt a broader range of recruitment strategies than initially planned, including financial incentives, reimbursement of travel expenses, simplified consent procedures and use of recruitment co-ordinators, [3, 6, 8-11]. Many RCTs fail to measure, report, or analyse the cost and efficacy of recruitment methods [12, 13]. A recent Cochrane review concluded that the impact of different recruitment strategies remained unclear [9]. Further research therefore is needed to investigate the efficacy of recruitment strategies for RCTs.

We evaluated the effectiveness of the recruitment strategies utilised by the Oxford site of the Staying Well After Depression RCT that is investigating the efficacy of Mindfulness-Based Cognitive Therapy (MBCT) in preventing relapse to depression and reducing the incidence of suicidal symptoms in comparison to a control psychological intervention and treatment as usual (trial protocol outlined in [14]). We describe each recruitment strategy and evaluate the effectiveness of the strategy in terms of (i) the recruitment return, including the number of participants who contacted the trial and the number who ultimately were randomized, and (ii) cost-effectiveness, including financial and human resource costs, as cost per participant. We also compared sociodemographic characteristics of individuals recruited from different sources. We conclude by discussing specific problems which occurred during recruitment and methods for overcoming these potential barriers.

Methods

Study Context

The recruitment strategies we describe were utilised within the context of the Staying Well after Depression randomized controlled trial [14]. The trial aims to investigate whether Mindfulness-Based Cognitive Therapy (MBCT), an 8-week treatment combining mindfulness meditation and cognitive therapy for depression, is effective in preventing relapse to depression and reducing the incidence of suicidal symptoms in those with a history of suicidality, when compared with Cognitive Psycho-Education (CPE) and treatment as usual (TAU). The detailed inclusion criteria have been published elsewhere [15]. The multi-centre trial operated from two UK research sites, Oxford and Bangor. The recruitment target was 360 participants in order to achieve a sample of 300 given a likely 20% attrition rate. We report on the recruitment strategies utilised within the Oxford site alone. Ultimately, 153 participants were recruited to the RCT at the Oxford site.

Recruitment Procedure

Participants were recruited in Oxford between October 2008 and October 2010. Once an interested candidate contacted the research group, by either a toll-free telephone number or dedicated email address, the research team carried out an initial telephone screening to assess eligibility for the trial. Participants were sent appointment reminders for on-site eligibility assessments and reimbursed for time and travel expenses to limit potential financial barriers to participation.

All recruitment data analyzed in this paper were taken from a recruitment database kept throughout the trial. The database was used to record the source by which a potential participant heard about the trial, contact information, the date potential participants initially contacted the trial team, the date they were screened, and whether they were eligible for the first in-person assessment.

Recruitment methods were selected prior to trial commencement through searches of the advertising opportunities available in the area and liaising with colleagues with experience in conducting RCTs. However, the recruitment strategies employed continued to evolve over the course of the trial depending on what was available and whether any types of recruitment method had been exhausted (for example, local community websites which no longer generated any new participants were removed). New procedures were initiated in response to opportunities which presented themselves (for example, mental health exhibitions).

Because treatment was delivered in groups, individuals were recruited in six cohorts to coincide with the start of the classes. Recruitment therefore was conducted in discrete recruitment phases to coincide with recruitment for the six cohorts. Recruitment phases began approximately 12 weeks prior to the treatment phase and, depending on the intake, continued until recruitment for that cohort was complete or until commencement of the treatment phase. The recruitment phase for each cohort lasted approximately three months.

Screening Procedure

Potential participants who satisfied initial eligibility criteria were invited to attend an in-person assessment. The double screening procedure was useful as it allowed the research team to answer questions and establish a rapport with potential participants with the goal of reducing attrition. Candidates who were deemed eligible for participation following the in-depth face-to-face assessment were invited to attend a second data collection appointment and were randomized to one of the three conditions (CPE, MBCT or TAU). After the eight week treatment phase, participants were invited to attend assessment appointments immediately and then at 3, 6, 9 and 12 months after randomization. The assessments at 3, 6 and 9 months lasted approximately half an hour; otherwise assessments usually lasted between one and three hours. All participants were offered their treatment of choice once their time in the trial had ended.

Recruitment Strategies

Whenever participants stated that they had contacted the research team via more than one method, the first method mentioned was used in analysis.

Eight recruitment strategies were utilised:

1. Newspaper advertising—A total of thirty-two advertisements were used during the trial. Newspaper advertisements could be resized and reused according to the space available. The price of each advertisement varied considerably depending on the paper, the size and colour used in the advertisement, the page on which it was displayed, the day the newspaper was sold, and the varying needs of the newspaper to fill space and was subject to negotiation. Prices ranged from £55 to £1000 per advertisement with the cheaper ones displayed in two local County newspapers and the most expensive being a full-page advertisement aimed at a specific population and accompanied by an article about the trial. The overall average price for a newspaper advertisement was £181. The cost-effectiveness of *individual* newspapers or advertisements was not examined because many candidates did not remember the specific newspaper in which they had seen the advertisement.

2. Web-Based Advertising—Advertisements were placed on a local community-based website in two locations, one on the current jobs page and one on the current local volunteer opportunities page. We also created a Facebook thumbnail advertisement, which was displayed to people aged between 18 and 70 years of age who lived within the Oxfordshire area; the cost varied depending on how many times and to how many people the advertisement was displayed. Additionally, we created a trial-specific website (<http://www.staying-well.org>) which included information about depression and about the trial (including detailed information on eligibility) and contact information for the recruitment team.

3. Advertising at exhibitions—We conducted three manned presentations. The first was at a one-day Mental Health Exhibition in London. The second and third were at local shopping centres for one day each. Permission was acquired for the shopping centre presentations; a participation fee was paid for the Mental Health Exhibition. Additional costs incurred included the cost of materials, i.e., table and chair rental, creation of a banner, business cards and pens.

4. Radio advertising—The trial was advertised on a local radio station 12 times a day at varying times over a one-month period and later for one week. The radio station created the advertisement based on the recruitment poster with guidance from the research team; we formulated the marketing plan, i.e. how many times the advertisement would air and when. The radio advertisement provided basic information about the study, contact details for the recruitment team, and a text-back service that allowed people to text the word “Well” to a six digit number which provided the recruitment team with an automated email containing the candidate’s telephone number and provided the candidate with the trial web address.

5. Advertising on buses—We employed a professional advertising agency to advertise the trial on local buses. Specifically designed posters (adapted from the existing trial posters) were displayed on the inside of local buses on two routes in Oxford City for a one-month period and thereafter as long as the space remained available. Advertisements on buses are employed by the local NHS trusts, for example, to advertise health services, as well as by corporate enterprises including gyms, hotels etc.

6. Poster advertising—Posters were displayed in waiting rooms of local general practitioner (GP) surgeries, local shops and shopping centres, libraries, community centres, sports halls and colleges. Posters also were sent to Oxford County Councillors, local church leaders, teachers, occupational health services at the local universities, colleges, and other major employers, local trades union organisations and so on, so that these people and organisations

would be aware of the trial and interested employees could contact us or pass the information on to any potential participant. Posters were distributed in person on main shopping streets in the areas surrounding the research centre. We also employed a local community information service to deliver posters to local businesses and community centres. Posters were refreshed at regular intervals to maintain continuous coverage in key community locations. The design (but not the text) of posters was modified periodically so that potential participants were not habituated to the same images.

7. General Practitioner referrals—Several GP practices in Oxfordshire were contacted through the Thames Valley Primary Care Research Partnership and invited to participate in trial recruitment. The research team met with interested GPs to explain the RCT. Following these meetings, GPs provided information about the trial during routine visits with patients whom they judged to be eligible. Additionally, six GP practices searched their databases for eligible patients and sent them a letter asking those who were interested in participating in the trial to get in touch with the recruitment team. GP practices differed considerably in their methods of coding diagnoses and hence the ease with which they were able to identify potentially eligible patients and in the extent to which they screened patients following identification through a generic database search. The research team compiled the information packs for the GP practices to send to potential participants and were given no access to patient data. Practices received an incentive of £20 per person referred and randomized into the trial.

8. Mental health care referrals—The recruitment team contacted and provided information about the trial to local Community Mental Health Teams, psychiatrists, psychologists, counsellors and Cognitive Behavioural Therapy (CBT) Therapists so that they could refer suitable candidates to the trial. Interested candidates contacted the research team directly.

9. Word of mouth—A number of candidates contacted the recruitment team after hearing about the trial from a family member or friend. Therefore, we have included word of mouth as a recruitment method in our analysis.

10. Referrals by charitable organisations—Although not initiated by the trial team, a number of caregivers and volunteers of charitable organisations, such as Mind, passed on information about the trial to potentially interested individuals. This method of recruitment has been distinguished from word of mouth because referral came from people employed in caregiving professions as opposed to a friend or family member who had heard about the trial.

Analytic Strategy

We evaluated the efficacy of each recruitment source based on the number of candidates who contacted the research team and the number of eligible candidates who subsequently were randomized into the trial (i.e., participants) and the cost-effectiveness of each strategy. The sample size for the current study is the number of contacts for whom basic demographic information (age and gender) was available; when calculating recruitment return as percentages, the total number of contacts was used.

For the purpose of comparing the overall success of recruitment sources the total *financial cost* of each method (the price) was combined with the *amount of time* taken to implement each method (manpower) to calculate an overall cost. Time (manpower) was transformed into a monetary value by calculating the approximate total hours taken for each method and multiplying each by an hourly rate of pay (£19 per hour as the total cost of a Research Assistant, including salary, tax, and national insurance). We also compared the sociodemographic characteristics of candidates and participants recruited through the different methods.

Results

Recruitment Return

The number of initial contacts received by the Oxford site was 1343. Of these contacts, 153 were eligible and randomized into the trial. The source by which a potential participant heard about the trial was available for 1154 of the 1343 people who contacted the trial (86%), with missing data arising largely from people who made contact by telephone or email but who were un-contactable thereafter. The number of initial contacts and randomized participants are shown in Figure 1.

As shown, web-based advertising returned the highest number of randomized participants ($n = 37$, 24.2%) and the second highest number of initial contacts ($n = 300$, 22.3%), including local community-based websites ($n = 197$, 14.7%), the trial website ($n = 100$, 7.4%) and a Facebook thumbnail advertisement ($n = 3$, 0.2%).

Poster advertising returned the second highest number of randomized participants ($n = 30$, 19.6%) and a high number of initial contacts ($n = 123$, 9.16%).

Radio advertising returned the third highest number of randomized participants ($n = 26$, 17%) and the highest number of initial contacts ($n = 412$, 30.7%). Approximately 12 people contacted the team per day having heard the radio advertisement.

GP referrals returned the fourth highest number of randomised participants ($n = 18$, 11.8%) and a large number of initial contacts ($n = 116$, 8.6%).

Learning about the trial by word of mouth returned a moderate number of people randomized to the trial ($n = 16$, 10.5%) and contacting the research team ($n = 46$, 3.4%)

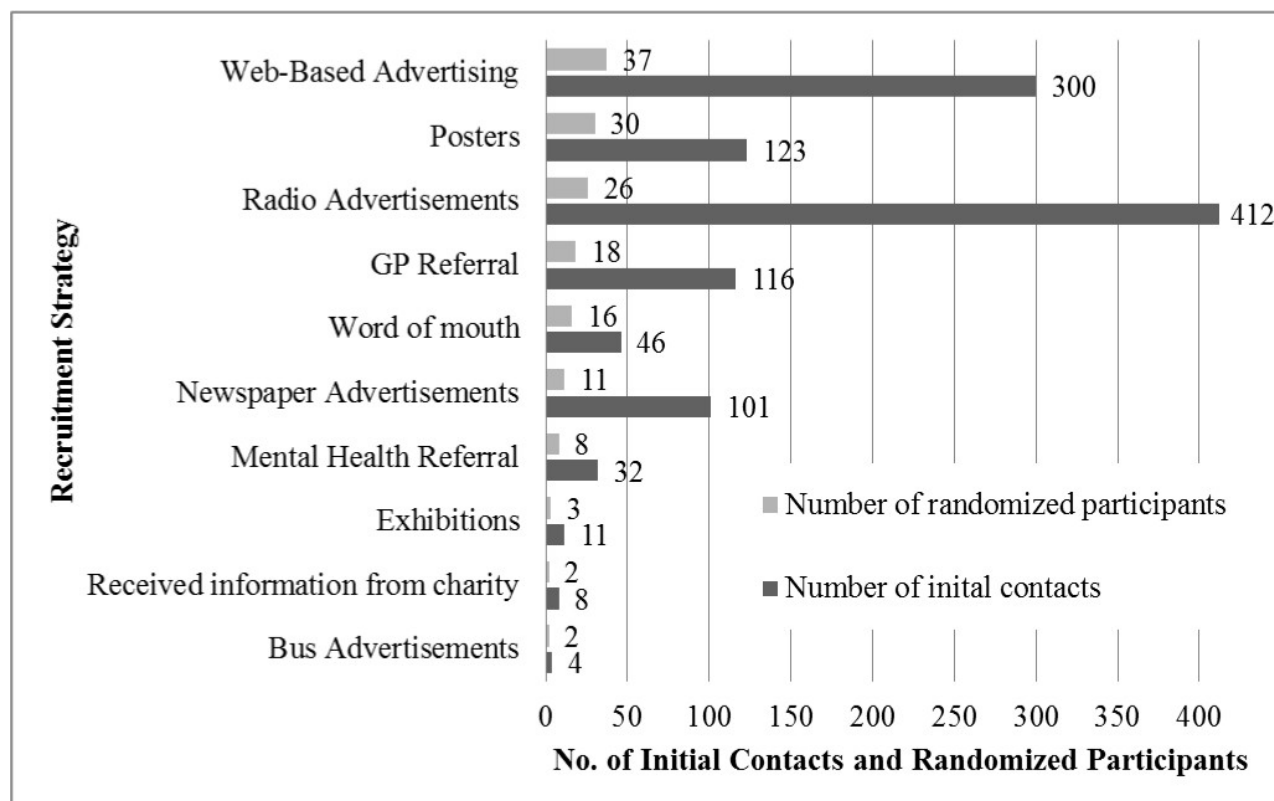


Figure 1. The number of initial trial contacts where recruitment source is known and randomized participants by recruitment source.

Cost Effectiveness

The cost for each recruitment strategy is presented in Table 1. The most cost-effective method of recruitment utilised was posters; although they were time-consuming to implement because of their repeated creation and maintenance, their return was large at an average cost of £69 per randomized participant. Web-based advertising was the second most cost-effective, as it was one of the least time-consuming strategies with low direct costs and high return at £105 per randomized participant. The third most cost-effective method was referral by mental health professionals because the cost to implement was low and the number of eligible contacts was high, equating to £178 per randomized participant. The direct cost of radio advertising was the highest, but as this method was one of the quickest and most efficient, it was the fourth most cost-effective method at £241 per randomized participant. Recruitment via GP referrals was expensive and time consuming but, when considering the number of eligible referrals, was the fifth most cost-effective method of recruitment at £396 per randomized participant.

As seen in Table 2, methods differed markedly in the ratios of randomized participants to initial contacts, potentially reflecting differences in the ability of each method to attract suitable candidates. For example, a small percentage of all radio contacts ultimately were randomized, whereas a large percentage of initial contacts reporting a poster as the recruitment source were randomized into the trial.

Sociodemographic Data

Demographic data was not available for all initial contacts as these data were not obtained from people who were excluded at an early stage of screening.

We compared the available sociodemographic characteristics of participants by source for the five most cost-effective methods for recruitment of randomized participants (Table 3). There was little difference in the sociodemographic characteristics of the randomized participants by source.

Table 1. Cost breakdown for each recruitment strategy.

Source	Price	Manpower (hours)*	Total cost **	Total cost per initial contact	Total cost per randomized participant
^I Word of mouth	£0	£0 (0)	£0	£0	£0
^I Information from charity	£0	£0 (0)	£0	£0	£0
Posters	£636	£7,125 (375)	£2,061	£17	£69
Web-Based Advertisements	£2,456	£1,425 (75)	£3,881	£13	£105
Mental Health Care Referral	£0	£1,425 (75)	£1,425	£45	£178
Radio Advertisements	£5,971	£285 (15)	£6,256	£15	£241
GP Referral	£0	£7,125 (375)	£7,125	£61	£396
Bus Advertisements	£1,000	£143 (7.5)	£1,143	£286	£571
Newspaper Advertisements	£4,575	£4,275 (225)	£8,850	£88	£805
Exhibitions	£1,985	£5,700 (300)	£7,685	£699	£2,562

^I These recruitment methods were not implemented by the research team but did draft a number of people to the trial so were included in the analysis

* Manpower was calculated by using the approximate hours for administrating each source and multiplying that by £19 for an hourly rate.

** Total cost was calculated by summing the price and manpower cost.

Table 2. The percentage of people recruited by strategy who were ultimately randomized for the five methods which recruited the most randomized participants.

Source	Contacts	Randomized	% strategy randomized
Website	300	37	12.3%
Poster	123	30	24.4%
Radio	412	26	6.3%
GP Referral	116	18	15.5%
Mental Health Referral	32	8	25.0%

Table 3. Sociodemographic information for the five methods which recruited the most randomized participants.

Source	Randomized Participants				Initial Contacts			
	%	% White			%	% White		
	Total	Women	Av. Age	British	Total	Women	Av. Age	British
Website	37	76%	41	92%	300	62%	40	90%
Poster	30	50%	47	97%	123	62%	47	97%
Radio	26	58%	43	96%	412	67%	43	96%
GP	18	83%	43	89%	116	77%	45	89%
Mental Health	8	75%	36	88%	32	78%	36	88%

Note- Gender is known for 96% of website contacts, 99% of contacts due to posters, 72% of radio advertising contacts, 100% of referrals from general practitioners and 100% of mental health referrals. Age and ethnicity are known for fewer initial contacts. Data are available for all randomized participants.

Discussion

We examined the recruitment strategies utilised at one site of an RCT seeking to recruit participants who had been depressed in the past but who were currently well. The recruitment strategies used in this trial were effective; 153 participants of a target of 180 were randomized at the Oxford site. Although not optimal, we were pleased to reach 85% of the sample target. For eligible participants enrolled, using posters and advertising online were the most cost-effective methods of recruitment. For attracting initial contacts, advertising online and on a local radio station were the most cost-effective recruitment methods. We found that the cheapest recruitment strategies were not always the most efficient when considering manpower cost and recruitment return. The most expensive strategies initially were cost-effective when manpower use was low and recruitment return was high. The comparatively large number of eligible participants recruited from posters may have been due to their location; many were posted in the waiting rooms of local GP surgeries which are likely to have significant through-flow of people who are oriented to health information. Posting information in GP surgeries also communicated that the study had been approved by the practice which may have increased trust.

Using GP referral as a recruitment method, although free to implement in terms of direct costs, nevertheless required considerable human resources and generated a low percentage of initial contacts and randomized participants. GP databases could not identify whether patients were currently well or unwell. Thus, this referral source may be more appropriate for recruiting patients who are unwell. Fewer men than women were referred by GPs, supporting the notion that men are less likely to seek treatment for mental health issues.

The ability to include background information is a significant advantage of web-based advertising over other methods, particularly compared to methods where the advertisement had to be compact, e.g. posters or newspaper advertisements. The most successful of the web-based advertisements were those on the local community-based websites, possibly because users tended to live in the vicinity of the trial site and therefore were able to participate. Slightly more men than women reported web-based advertising and posters as their recruitment source, perhaps because those advertising strategies were private, as opposed to referral by a GP or a mental health professional.

Although many people contacted the recruitment team after having seen the trial website, we do not know how they located the site. Nevertheless, having a comprehensive and attractive website which was well maintained was important as the website was used as a source of information about the trial by many potential participants.

Mental health professionals tended to have a sound understanding and knowledge of disorders and understood the inclusion criteria, so already had screened people before referring them to the trial. In our experience, these care-givers are supportive of a trial in which their clients can take part without cost and receive a potentially life-changing treatment, thereby avoiding long NHS waiting lists.

Radio advertising was expensive but returned a large number of potential participants; however, the radio advertisements were more effective than anticipated so extra research staff was needed to contact all of the responders, resulting in unforeseen cost. Had the effectiveness of this type of recruitment been known in advance, we might have been able to screen a larger proportion of these candidates and increased the number randomized into the trial. The text-back service used may have contributed to the large number of responses by making it easier for people to get in touch, but this service also may have contributed to the small proportion of randomized participants. Indeed, when called by the trial team, some candidates already had concluded that they were ineligible after having read information on the trial website. The radio station used for advertising the trial was a local one so candidates were likely to live within a practical distance from the research site.

We identified a number of problems during the recruitment process. The time between the initial telephone screening and the face-to-face assessment was sometimes excessive. As depression is a recurrent disorder, some initially eligible people had relapsed by the time of the in-person assessment and some people had become too busy to participate. Those unwell or too busy to participate were asked whether they would like to be re-contacted at a later date. However, people who had been unable to participate initially usually were not eligible when assessed at a later date.

Limitations

Whilst we were able to quantify the cost effectiveness of different recruitment methods in terms of their initial direct costs and staffing resources, there are additional implications for staffing which we have not been able to quantify. Recruitment sources differed considerably in terms of the number of initial contacts who ultimately were randomized into the trial.

Table 2 shows the percentage ultimately randomized as a function of total contacts per method and thus gives some indication of the screening burden of ineligible candidates per method, but we did not formally incorporate this information into the cost effectiveness analysis.

Although data on recruitment source was available for most candidates, it was not available for those who left a telephone or email message but could not be contacted by the trial team. Consequently, it is possible that the efficiency of certain methods of recruitment was poorer than estimated. Likewise, often people had seen a number of advertisements and could not remember where they had learned about the trial. Thus it sometimes was difficult to establish exactly which recruitment method led people to contact the trial team.

A third issue is one of generalizability. It may not be feasible to generalize the recruitment methods used in this trial to other populations, such as those currently unwell, or to other geographical locations where different local services exist.

Further, candidates who contacted the trial team elected to be screened over the telephone and, if not judged ineligible, in person. Self-selection may have introduced some bias. Some eligible people may not have wanted to be screened for eligibility via telephone, particularly as depression may be a sensitive issue for people to discuss.

Finally the recruitment procedures evolved over the course of the trial depending on the effectiveness of each recruitment method and whether the team believed that a method had exhausted its potential. These changes may have yielded differences in participant or cohort characteristics over time. We do not have the necessary data from our trial, but it would be interesting to analyze recruitment cohort effects in future RCTs.

We were unable to evaluate the effects of recruitment incentives that included paying travel expenses for in-person

assessments, offering all randomized participants the opportunity to take part in a therapy class once their formal participation in the trial was completed, and providing a small fee to GPs of randomized participants to cover their administration costs.

Conclusions

Strategies to recruit RCT participants which seem expensive actually can be cost-effective when considering the resources utilised to implement them, and the number of contacts solicited and participants ultimately randomized into the trial. We encourage other trialists to describe recruitment strategies implemented and to report their effectiveness so that designers of future trials can utilise the information when selecting strategies to employ.

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