



## RESEARCH ARTICLE

**REVISED** **Prioritising key motivators and challenges influencing informal carers' decisions for participating in randomised trials: An embedded Study Within A before and after Trial (SWAT 55) [version 2; peer review: 1 approved, 1 approved with reservations]**

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**Abstract**

**Background:** Family members, or others, often assume the role of informal (unpaid) carers of people with chronic illnesses. Care-giving, however, can impact profoundly on the quality of life of carers and can cause carer worry, stress and guilt. Implementing interventions that positively affect the lives of carers is important; however, carers as a group are often difficult to reach. We embedded a study within a pilot-feasibility trial of a mindfulness based intervention to determine and prioritise the key motivators and challenges influencing informal carers' decisions for participating in a trial.

**Methods:** We used a multi-method approach involving interviews with participants from a 'host trial' and data from systematic reviews to develop a survey that was distributed to informal carers in Ireland. The survey consisted of 28 motivator and 17 challenge statements. Participants rated how important they thought each statement was when deciding to take part in a trial on a 5-point Likert Scale. Mean scores and standard deviations were calculated for each statement and arranged in descending order to provide the priority lists.

**Results:** Thirty-six carers responded to the survey. Helping to create awareness about carers was the top ranked motivator, followed by four study design statements related to the time at which the study occurs, the study location, format of delivery and venue. The least important motivator related to how carers were invited to take part in

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report



report

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Any reports and responses or comments on the article can be found at the end of the article.

a study. Difficulties in planning due to the caring role emerged as the most important challenge, followed by being unable to leave the care recipient on his/her own.

**Conclusions:** Insight into decision-making for research participation will assist trial developers tailor trial processes for informal carer populations. We recommend that trialists should consider these motivators and challenges when designing future trials involving informal carers so as to enhance trial feasibility and success.

### Keywords

Study Within A Trial, informal carers, survey research, trial participation, trial design.



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**REVISED Amendments from Version 1**

Based on comments from reviewers, minor amendments to the text were made, mainly in the discussion section to reflect that the results of our study might not be widely generalizable to all carers and that further research is needed.

**Any further responses from the reviewers can be found at the end of the article**

**Introduction**

The Health Research Board-Trials Methodology Research Network (HRB-TMRN) Ireland, in collaboration with the James Lind Alliance United Kingdom, participated in a priority setting partnership (PSP) to identify and prioritise unanswered questions around trial recruitment (the PRioRiT<sub>y</sub> study)<sup>1</sup>. The PSP culminated in a face-to-face meeting, attended by key stakeholders (members of the public, recruiting clinicians and researchers), where a top-10 list of unanswered priority questions on trial recruitment was agreed and ranked in order of importance. Ranked highly was a question on key motivators influencing members of the public decisions for participating in randomised trials (PRioRiT<sub>y</sub> question 6)<sup>1</sup>.

Family members, or others, often assume the role of informal (unpaid) carers of people with chronic illnesses. Care-giving, however, can impact profoundly on the quality of life of caregivers and can cause carer worry, stress and guilt. Family members providing unpaid care have been described “...as a *hidden patient group*...”<sup>2</sup>. Mindfulness based interventions have the potential to positively impact on the lives of carers by reducing caregiver depression, anxiety and stress, and by improving carer quality of life<sup>3</sup>. A randomised pilot-feasibility trial was planned by a Dublin-based university research team to test a mindfulness based stress reduction (MBSR) intervention, compared to no intervention, for informal carers of people with chronic illnesses in one region in Ireland. As informal carers represent a geographically disperse discrete group within the general public who might face specific challenges when deciding to take part in a trial, the MBSR trial presented an excellent opportunity to embed a Study Within A Trial (SWAT). The SWAT was designed to ascertain and prioritise key motivators and challenges influencing informal carers’ decisions for participating in a trial, thus helping to advance the design and conduct of future trials in this, and other, similarly discrete populations. The SWAT protocol was prospectively registered with the SWAT repository as [SWAT-55](#).

**Context of SWAT-55**

The SWAT-55 host trial was a planned pilot-feasibility randomised trial (ClinicalTrials.gov identifier [NCT03048565](#), registered 9<sup>th</sup> February 2017) based on the following PICO (population, intervention, comparator, outcomes);

- Population: Informal carers, defined as a person (relative, neighbour, friend or significant other) providing personal

help, support or care for an individual (adult or child) with a chronic illness and who were not a paid health care provider. A person with a chronic illness was defined as an adult or child with a diagnosed condition of six months duration or longer. Access to carers was through [Family Carers Ireland](#), a registered charity representing carers in Ireland who agreed to distribute letters of invite via email to carers in the Dublin region.

- Intervention: A MBSR programme delivered over eight weeks (two hours/week) by a trained mindfulness teacher, with participants encouraged to practice mindfulness exercises between sessions.
- Comparator: No MBSR programme.
- Outcomes: Clinical outcomes were baseline and post intervention (up to two weeks from end of programme and six months follow-up) stress, mindfulness and quality of life data collected using self-report questionnaires. Pilot measures included recruitment processes, data collection methods and intervention delivery. Feasibility outcomes were recruitment success, time to recruit, attendance at classes, dropouts and participant satisfaction.

**Host trial sample size, randomisation and recruitment**

The planned sample size for the host trial, based on a recommended sample size for pilot studies of 30 per group<sup>4</sup> was 80 informal carers, or 40 per group allowing for a 25% attrition rate (10 participants per group) at six-months follow-up, randomised on a ratio of 1:1 using a computer-randomised number generator. Ethical approval to conduct the study was granted by the Research Ethics Committee of the lead researcher’s university. Recruitment to the host trial commenced in March 2017 with intervention delivery planned for April-June 2017. SWAT-55 was planned to commence in June 2017.

An invitation to participate in the host trial was emailed to 538 Dublin based registered Family Carers Ireland members. Intervention delivery was initially planned as face-to-face; however, by the end of August, despite efforts, two carers only were recruited and randomised to the intervention group, one of whom had to withdraw subsequently because he/she was unable to attend the intervention sessions. Following a Trial Steering Group (TSG) meeting, a decision was made to deliver the intervention in an online format and open the study to a wider national base. Ethical approval was granted, and an updated study invitation letter was circulated in September 2017. A social media invitation was also posted to the Family Carers Ireland Facebook page. By October 2017, 11 carers only were recruited to the study; five in the intervention group and six in the control. Following a further TSG meeting, a decision was made to change the trial design to a before and after trial, thus converting the host trial to a non-randomised pilot-feasibility trial<sup>5</sup>, on the basis that a randomised trial was not feasible at recruitment level. Participants recruited to the control arm of the original trial were subsequently offered the intervention, and the revised design was

further advertised. Between mid-October and end of December 2017, 17 carers were recruited to the study, 15 returned baseline data, of which seven returned end of intervention data (quality of life, mindfulness and stress outcomes). These challenges further emphasised the importance of SWAT-55 in exploring the reasons why informal carers, as a discrete group within the general population, may or may not decide to take part in a randomised trial. Although the original host trial was redesigned, we proceeded with the SWAT as planned, albeit as a study within a non-randomised trial, accepting that this deviated from our original intention of conducting the SWAT as a study within a randomised trial.

## Methods

### Design

A multi-method two-phase study was conducted. Phase 1 involved a series of face-to-face interviews with a sub-sample of participants from the host trial and a review of systematic reviews that assessed motivators or barriers for taking part in trials<sup>6-12</sup>. Resultant data from both the interviews and systematic reviews were used to collate a list of key motivators and challenges. Phase 2 was a national survey of how important these key motivators and challenges were to informal carers in making a decision on trial participation.

**Phase 1.** The host trial consent form provided participants with an option to agree to future contact for follow-up studies arising from the trial. Of the 17 carers recruited to the host trial, 11 agreed to future contact. These 11 carers were contacted via email (addresses provided as part of the host trial) and invited to take part in an interview designed to ascertain their views of and reasons (motivators and challenges) for participating in research. We aimed to recruit 10 participants for interview; however, only two came forward. The interviews, which were semi-structured using an interview guide (available at: <http://www.doi.org/10.5281/zenodo.4029385>), were held at a mutually agreed time and venue. The interviews were conducted by the lead author, a female Prof in Midwifery with 10 years' experience of sensitive interviewing in healthcare. The interviews were recorded and transcribed verbatim. The data was manually coded by two authors (VS and AH), and analyzed, based on a thematic analytical approach using discussion, iteration and consensus, to determine common categories of i) motivators and ii) challenges, for use in phase 2 of the study.

Due to limited participation in the interviews we made a necessary pragmatic decision to additionally draw on data from systematic reviews to inform phase 2. Seven systematic reviews of studies of reasons for participating in trials<sup>6-12</sup> were identified in an evidence mapping exercise conducted as part of the PRioRiTy study<sup>1</sup> based on a search of MEDLINE, EMBASE, Cochrane Database of Systematic Reviews, Social Sciences Citation Index and ERIC using a combination of search terms (e.g. "attitudes to trials":kw OR (participat\* or recruit\* or enrol\* or select\*) near/8 (trial\* or research or study):ti) from the Cochrane systematic review of strategies to improve recruitment to trials<sup>13</sup> and from the ORRCA project<sup>14</sup>. The reviews were identified as eligible for the evidence mapping exercise

in the PRioRiTy study<sup>1</sup> by at least two members of the Steering Committee. Data related to motivators/barriers for taking part in a trial were extracted onto an excel sheet for SWAT 55 by one author (VS) and corroborated by a second (AH). These data were combined with the data from the interviews to develop categories, inclusive of aligned motivator/challenge statements associated with these categories, for use in the phase 2 survey. An 'audit trail' of developing categories from initial codes was maintained to ensure confirmability of the process. Survey development occurred between January and June 2018.

**Phase 2.** Phase 2 was a national survey of informal carers in Ireland to prioritise the key motivators and challenges when making decisions to participate in a trial (hypothetical or real). Developed based on the findings from phase 1, the draft survey was reviewed by a carer for user-ability and by the National Adult Literacy Agency (NALA) for plain language and comprehension. Following a number of edits and language 'tweaks', the survey received the Plain English Mark and was finalized. Survey distribution, using SurveyMonkey, was planned for July/August 2018; however, as Family Carers Ireland were undertaking a survey of their own at the time, distribution was delayed, initially until September 2018, and subsequently to January 2019. The original agreement was for Family Carers Ireland to distribute the survey link to their database of registered members, accompanied by the study information leaflet and the lead applicant's contact details to discuss the study further, as needed. The survey was anonymous with no details of participant's names, locations, email addresses, or any other identifying details requested. At this time, however, uncertainty and concerns related to the new [General Data Protection Regulations \(GDPR\)](#) that had come into effect in 2018 prohibited email distribution, and the survey finally went live at the beginning of February 2019 via the Family Carers Ireland Facebook page, with closure four weeks later.

### Outcome measures

The study outcomes were a prioritised list of i) motivators and ii) challenges, based on the level of importance that respondents assigned to each of the survey's motivator and challenge statements.

### Data collection and analysis

Quantitative analytical techniques were used to aggregate individual's ranking of motivators and challenges. Each participant was asked to rank each motivator and challenge on a 5-point Likert scale of 1=very unimportant, 2=somewhat unimportant, 3=neutral/unsure of importance, 4=somewhat important, and 5=very important. Mean scores and standard deviations (SD) for each item were calculated using SPSS (version 21). The items were subsequently arranged in descending order of importance based on the mean and SD scores attributed to them. The priority list of informal carers' motivators and challenges for participating in trials was determined.

### Ethical statement

Ethical approval for this embedded study was granted by the Research Ethics Committee of the School of Nursing

and Midwifery, Trinity College Dublin (Ref: 17/07/2017). Consent for interviews was written and taken prior to commencing the interview. Consent for the online survey was indicated by an ‘I agree’ tab, which indicated the participants gave their consent to take part in the survey.

**Results**

**Interviews, systematic reviews and survey development**  
 The interviews, involving one male and one female, were of 21 and 38 minutes duration, respectively. One participant provided

full-time care, and the other part-time care. The care recipients were a child with cerebral palsy and an adult with multiple sclerosis. Although only two carers participated in the interviews, both provided valuable data for survey development. [Table 1](#) presents examples of the categories, and associated codes, which emerged from the analysis of the interview data.

The motivators and challenges data extracted from the systematic reviews, some of which overlapped with the emergent categories from the interview data, are presented in [Table 2](#).

**Table 1. Example categories and associated codes derived from interview data.**

Code	Category
Interested in the topic/area that is being studied	Personal Interest/Personal Gain
Helps with reducing isolation and loneliness	
Would do me good	
How information is delivered	Trial Information
Use of simple language	
Keep it simple	
How the study information is delivered	
Use of leaflets/email	Trial design
Study location	
Prefer face-to-face	
Online is preferable	
Location where the study is being held	
Time of day that study is being held	
How the intervention is delivered	
Person/institution who is running the study	
Choice of online/face-to-face	Personal risks
Topic being studied	
Condition of care-recipient	
Unpredictability of carers role	Carer identity
Getting voice heard	
Differentiating groups (caring for child or adult)	Common good
Feeling (under)-valued as a carer	
Might change things	
Doing research is important	
Access to doctors	
Helping carers/might help carers	Common good
Taking part in research will help carers	

**Table 2. Systematic review data.**

Reference	No. of included studies	Motivators data	Challenges data
Limkakeng <sup>9</sup>	14	Perceived health benefits for themselves Altruism	Mistrust of researchers Being 'guinea pigs' Fear of potential risks Problems with informed consent
Nalubega & Evans <sup>10</sup>	21	Perceived benefits for themselves and others Previous research experience	Fear and uncertainty around taking part Disapproval by family and friends Time constraints Financial burden Lack of understanding about the research
Rivers <sup>7</sup>	31	Friend/relative with previous research experience or friends/ family recommendation Accessibility - sufficient staff, services at non-traditional hours Prioritising the enrolment of minorities	Mistrust and negative perception of controlled clinical trials Lack of knowledge about ongoing research Impact of faith/religious beliefs on participation Financial constraints, lack of transportation and childcare
Wilman <sup>11</sup>	49	Perceived benefits for themselves and others Being involved in decision-making Support from doctor or spouse	Research perceived as an inconvenience Concerns over risks involved Time constraints Problems with informed consent
George <sup>8</sup>	44	Culturally congruent study designs Perceived benefits for themselves and others Community-based recruitment Adequate remuneration	Mistrust and consequent fear of participation Stigma related to topic of research Competing demands
Mills <sup>6</sup>	33	-	Protocol issues (possibility of placebo, potential side-effects) Potential negative impact on quality of life
Tromp <sup>12</sup>	38	Individual health benefits Altruism Trust in safety of research and relation to researcher Increasing comfort by participation	Fears of potential risks Distrust in research- 'guinea pigs' Logistics/disruption to daily life Research perceived as a burden for the participant

Using the results of the interviews and the systematic reviews, core categories, with related motivator/challenge statements, were developed. The final survey consisted of five core motivator categories with 28 associated statements and two core challenge categories with 17 associated statements. The motivator categories were; carer identity (three associated statements), study design (12 associated statements), altruism/common good (four associated statements) personal interest (six associated statements) and study information (three associated statements). The challenge categories were personal risk (11 associated statements) and study design (six associated statements).

### Survey findings

Thirty-six informal carers returned a completed survey. The majority of respondents were  $\geq 36$  years of age, female, educated to minimum leaving certificate level and unemployed (Table 3).

When asked to indicate with whom they lived, some respondents' ticked more than one response option (e.g. lived with partner and children). Two respondents indicated living on their own, and the remainder reported living with a partner (n=22), their children (n=19), their mother (n=7), their father (n=2) and with siblings (n=2). Twenty-nine of the 36 respondents (81%) lived in the same residence as the person they were caring for. The majority of participants were more than 10 years in their caring role (61%; n=22), followed by 2–5 years (19%), 6–10 years (17%) and <2 years (3%). Thirty-three respondents (92%) reported that they provided care on a full-time basis, with the remaining three (8%) providing care part-time. The care recipients (n=38 as some respondents indicated they cared for more than one person) in most cases, were children (n=16), followed by parent(s) (n=10), partner/spouse (n=9) and sibling(s) (n=3). Five care recipients were under the age of

**Table 3. Respondent's demographics.**

Demographic	Category	Number (%)
Age (years)	18-25	1 (3%)
	26-35	0
	36-45	9 (25%)
	46-55	12 (33%)
	≥ 56	14 (39%)
Gender	Female	34 (94%)
	Male	2 (6%)
Education	No formal qualifications	0
	Primary or first school	0
	Group or Junior certificate, 'O' levels /GCSE, or equivalent	3 (9%)
	Leaving certificate, 'A' levels, NCVA level 1 certificate, or equivalent	11 (31%)
	Third Level Bachelor Degree	13 (37%)
	Postgraduate Master's degree or PhD	8 (23%)
Employment status	Unemployed	14 (39%)
	Part-time paid work	7 (19%)
	Retired	4 (11%)
	Unable to work due to illness/disability	3 (8%)
	Full time paid work	3 (8%)
	Student	2 (6%)
	Casual paid work	1 (3%)
	Other (e.g. carers leave)	1 (3%)
	Not answered	1 (3%)

17 years, seven were aged 18 to 29, six were aged 30 to 39 years, and the remaining 18 were aged over 40 years. Of these 18, 14 were 60 years or older. Most respondents (78%; n=22) had not received any training for their role as an informal carer. Of those that did, some indicated previous professional training (e.g. nursing, disability or mental health) or varied short training courses, for example, manual handling, infection control, pain management or courses on autism spectrum disorder. The condition of the care recipients varied widely, with many respondents caring for people with multiple conditions, and comorbidities; for example, Alzheimer's/Dementia/Parkinson's (n=8), Motor Neurone Disease/Multiple Sclerosis (n=2), Autism/autistic traits (n=5), Downs Syndrome/other intellectual disability (n=6), brain/spinal injury (n=2), mental ill-health (n=2), emphysema (n=1) and cancer (n=1).

**Priority list of motivators.** Table 4 provides the list of motivators prioritised by the mean and SD scores attributed to

each motivator statement. Helping to create awareness about carers was the top ranked motivator for participating in a trial, followed by four study design categories related to a suitable time at which the study occurs, the study location, format of delivery (i.e. online) and venue. The least important motivators for deciding to participate in a trial, from the carers' perspectives, related to study information issues; that is how they were informed of or invited to take part in the study, with all three associated statements averaging mean importance scores of 3.5 or less.

**Priority list of challenges.** Table 5 provides the list of challenges prioritised by the mean and SD scores attributed to each challenge statement. Personal risk, associated with difficulties in planning due to the caring role emerged as the most important challenge for carers when deciding on participating in a trial (mean 4.13, SD 1.25), followed by being unable to leave the care recipient on his/her own. Not

**Table 4. Priority list of motivators.**

Rank	Motivator	Mean (SD)	Category
1	The research will help create awareness about carers	4.40 (1.30)	Carer identity
2	The study is held at a time that suits me	4.39 (1.23)	Study design
3	The study is held at a place that is easy to find and easy to travel to	4.26 (1.29)	Study design
4	I can take part in the study online	4.19 (1.34)	Study design
5	The study is held at a place I feel comfortable in	4.16 (1.27)	Study design
6	Taking part will help researchers get valuable information about carers and their needs	4.15 (1.41)	Altruism/common good
7	The researchers understand the different issues carers face when caring for a younger person or an older person	4.13 (1.38)	Carer identity
8	I am very interested in the topic being studied	4.13 (1.41)	Personal interest
9	By taking part, carers might get more access to doctors or useful information	4.10 (1.32)	Altruism/common good
10	It is simple and easy to understand what is being studied and why	4.06 (1.30)	Study design
11	Doing research is important	4.06 (1.39)	Altruism/common good
12	I am interested in research on carers	4.06 (1.46)	Personal interest
13	The language used is easy to understand	4.03 (1.30)	Study design
14	The study treats carers for a younger person and carers for an older person as unique groups with different needs	4.03 (1.38)	Carer identity
15	New research might help carers in their day-to-day lives	4.00 (1.46)	Altruism/common good
16	Taking part will make my voice heard	3.97 (1.38)	Personal interest
17	I trust the institution running the study	3.97 (1.40)	Study design
18	I can choose how I take part in the study (for example, online or face-to-face)	3.90 (1.40)	Study design
19	I trust the person running the study	3.84 (1.19)	Study design
20	By taking part, I might gain access to doctors or useful information	3.80 (1.45)	Personal interest
21	Being asked to take part in the study makes me feel valued	3.74 (1.24)	Personal interest
22	Taking part in the study would benefit me socially (for example, reduce isolation or provide company)	3.55 (1.48)	Personal interest
23	I was invited to take part by a carer support group	3.48 (1.06)	Study information
24	I know the institution running the study	3.35 (1.02)	Study design
25	I can take part by talking with someone face-to-face	3.26 (0.97)	Study design
26	I found out about the study through a friend or family member	3.00 (0.97)	Study information
27	I found out about the study through a leaflet	2.97 (0.75)	Study information
28	I know the person running the study	2.84 (0.97)	Study design

knowing the person running the study was deemed to be the least important challenge for carers when deciding to take part in a trial (mean 2.74, SD 1.18).

## Discussion

This embedded study within a non-randomised pilot feasibility trial has identified and highlighted important factors from

the perspectives of a small number of carers that may influence decision-making on trial participation. As the focus of healthcare internationally is to increase community-based care and avoid admission to secondary healthcare facilities for as long as possible<sup>15</sup>, compounded by a rapidly increasing older person population<sup>16</sup>, many individuals may find themselves in a caring role for which they are ill-prepared<sup>17,18</sup>. Evaluating



**Table 5. Priority list of challenges.**

Rank	Challenges	Mean (SD)	Category
1	Life as a carer makes it difficult to plan ahead	4.13 (1.25)	Personal risks
2	The person I care for cannot be left alone (I do not have anyone else to take care of them)	4.09 (1.28)	Personal risks
3	Life as a carer makes it difficult to find time to take part in a research trial	4.04 (0.83)	Personal risks
4	I cannot travel to the place the study is held in	3.78 (1.28)	Study design
5	The study is held in a place I might not feel comfortable in	3.65 (1.27)	Study design
6	The language used in the study is hard to understand	3.64 (1.18)	Study design
7	I do not trust the institution running the study	3.52 (1.28)	Personal risks
8	I do not trust the person running the study	3.48 (1.28)	Personal risks
9	Taking part in a study would interfere with my daily life	3.39 (1.23)	Personal risks
10	The research does not directly affect carers	3.39 (1.31)	Personal risks
11	I do not know the institution running the study	3.09 (1.08)	Personal risks
12	I am not interested in the topic being researched	3.09 (1.35)	Study design
13	I do not believe the research will help carers	3.09 (1.51)	Personal risks
14	The topic being studied makes me uncomfortable or upset	2.96 (1.19)	Personal risks
15	I can only take part in the study online	2.96 (1.30)	Study design
16	The study requires me to talk to someone face-to-face	2.95 (1.13)	Study design
17	I do not know the person running the study	2.74 (1.18)	Personal risks

interventions to support informal carers psychologically, socially, physically, or otherwise, is important. As a discrete group within the general population informal carers can be a hard to reach population, not least of all because of regional dispersity<sup>19</sup> and the cost, time and inconvenience that might be associated with taking part in a trial<sup>19,20</sup>. Furthermore, where trials do recruit, attrition rates in studies on carers can be high, for example, from 25% to >40% across studies<sup>21,22</sup>.

Understanding informal carers' views of research will assist trial developers, and other researchers, accommodate their unique needs. Carer identity, specifically, research that will help raise awareness about carers was the number one collectively identified motivator for trial participation. This supports the earlier quote describing informal carers as a '*hidden patient group*'<sup>2</sup> and gives consideration to a sense of isolation or loneliness that carers may experience in their caregiving roles. Trial developers and researchers, in efforts to enhance participation in trials involving informal carers, need to consider the explicit demands that the caring role places on carers. These, in particular, identified in this study, were difficulties with planning ahead (number 1 priority challenge) and being unable to leave the care recipient alone, or for any length of time, all

of which have implications for the design of any future, similar, host trial.

#### Implications for a future host trial

The non-feasibility of the host trial in recruiting sufficient participants implies that any plan for a future, similar trial needs to take cognisance of carers' motivators and challenges, and would require a major rethink as to how the trial would be designed and implemented. Although our study has highlighted important motivators and challenges it is not possible to generalise these findings directly to a host trial as our findings are based on few carers. However, the results provide areas that developers of future trials may consider; for example, how informal carers come to know of a study (e.g. through a family member or friend, or through a leaflet), or their awareness of those conducting the study, were ranked overall, as being neutral or unimportant when deciding to take part in a trial. Thus focusing on aspects of trial design, such as the value the trial has for carers' identity, and how the intervention is delivered may be of greater value. Furthermore, as carers in this study identified that their caring role leaves it difficult for them to plan ahead, to have time away from their care recipient, or to travel to study locations, this

might may prompt consideration for offering the intervention online or, if offering it face-to-face, plan for the interventionist to travel to the participants homes or other location convenient to them. These would likely have resource implications, however, in terms of personnel required and expense; an element that would need to be factored in to the future trial's processes and budget.

### Challenges to conducting the original planned SWAT 55

A number of challenges in conducting the originally planned SWAT were encountered which may limit the results. These included limited recruitment to the host randomised trial and a redesign to a before and after trial resulting in a reduced purposive sampling frame for phase 1 of the planned SWAT. Although rich data were provided by the two interviewees from the before and after trial, a wider pool of participants might have better ensured, or at least increased our confidence in data sufficiency. This was overcome somewhat, however, by the extraction of data from related systematic reviews, combining these data with the interview data in developing the survey.

Despite extensive efforts, 36 participants only responded to the national survey, which is likely to represent a very small proportion of the population of informal carers across Ireland. Although we cannot be sure, the inability of Family Carers Ireland to distribute the survey via their email list, and the move towards distribution via Facebook (with only 12 'shares' and 14 'likes' noted), may have impacted on the survey response rate. Furthermore, other than a request to snowball the survey, we did not consider other networks where carers might have been recruited; this was a probable oversight as had we extended our advertisement to other networks at the time, it may have increased participation. Had a larger number responded, providing greater caregiver representation, the ranked priority list of motivators and challenges might ultimately be different. The difficulties encountered with recruitment, however, could relate to how individuals identify with the concept of caring as evidence suggests that many individuals do not formally identify themselves as a carer or in a caregiving role<sup>23</sup>. For example, in a qualitative study of 40 relatives or friends, the researchers concluded that "...self-identification with the role and label of carer is nuanced, shifting and variable"<sup>24</sup> and refers to other studies that have shown variation in how relatives identify with the term carer<sup>25,26</sup>. In one study, for example, exploring recruitment with carers of people with multiple sclerosis, participants suggested using the term 'support' or 'assistance' in place of the term 'caregiver' and highlighted that many people would not consider themselves to be carers<sup>23</sup>. This is an important consideration for researchers when advertising trials to an already hard to reach population, and how carers, including their associated roles, are described may need to be considered within trial participant information.

### Conclusion

Insight, albeit from the perspectives of a small sample of carers in Ireland, as to the motivators and challenges that influence informal caregivers' decisions for research participation, has been offered by this embedded study. These findings provide some insight for trial developers and researchers to consider in tailoring trial design and associated processes for informal caregiver populations, and add to what is a limited evidence base. Consideration of these motivators and challenges to enhance participation has the potential to increase trial feasibility and success and reduce research waste. Further research, however, is required to both substantiate and expand on these findings, and how barriers faced might vary according to the needs of the individual being cared for.

### Data availability

#### Underlying data

Access to interview transcripts are restricted under Research Ethics Committee approval as even de-identified transcript data may contain information that could potentially identify a participant based on statements made, phrasing, or personal data contributions which presents a potential breach in GDPR assurances. Transcripts may be made available, in full or in part, on individual request and only with the explicit permission of an interviewee based on the acceptability of the nature and reason for the request. Such requests such be made to the corresponding author ([smithv1@tcd.ie](mailto:smithv1@tcd.ie)) in the first instance.

Zenodo: SWAT 55 survey and dataset. <https://doi.org/10.5281/zenodo.4029385><sup>27</sup>.

This project contains the following underlying data:

- SWAT 55 Survey (participant responses).xlsx

#### Extended data

Zenodo: SWAT 55 survey and dataset. <https://doi.org/10.5281/zenodo.4029385><sup>27</sup>.

This project contains the following extended data:

- Interview Schedule.docx
- SWAT Survey (Final Version).pdf

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by/4.0/) (CC-BY 4.0).

### Acknowledgements

We sincerely thank the carers for their time in taking part in this study. We thank Family Carers Ireland for their assistance in distributing the survey link through their Facebook page.

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## Open Peer Review

Current Peer Review Status:  

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### Version 2

Reviewer Report 17 June 2021

<https://doi.org/10.21956/hrbopenres.14395.r29557>

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**Elizabeth Randell**

Centre for Trials Research, Cardiff University, Cardiff, UK

Many thanks to the authors for their responses.

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Intellectual disability and autism

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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### Version 1

Reviewer Report 28 January 2021

<https://doi.org/10.21956/hrbopenres.14235.r28738>

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**Terry A Badger**

College of Nursing, University of Arizona, Tucson, AZ, USA

A clearly presented SWAT, including providing insight why carers do not participate in clinical trials. There are a number of limitations to this study, especially the phase 1. Findings from two carers are unlikely to have achieved data saturation calling into question using this information to develop the survey. It would be important to have more detail about the interview methods and

how authors maintained rigor.

Recruitment from a national network was good, however the fact that so few responded in of itself is problematic.

Surveys are usually not well received, it would be helpful to know what other methods were used beyond mailing them. The discussion is too broad and goes beyond the data. Likely this study needs to be replicated with a larger sample in both phase 1 and two. Manuscript would benefit from revision.

**Is the work clearly and accurately presented and does it cite the current literature?**

Yes

**Is the study design appropriate and is the work technically sound?**

Yes

**Are sufficient details of methods and analysis provided to allow replication by others?**

Partly

**If applicable, is the statistical analysis and its interpretation appropriate?**

Partly

**Are all the source data underlying the results available to ensure full reproducibility?**

Partly

**Are the conclusions drawn adequately supported by the results?**

Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** PsychoOncology: Symptom management interventions for Cancer Survivors and Caregivers.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

Author Response 07 Feb 2021

**Valerie Smith**, Trinity College Dublin, 24 D'Olier Street, Dublin, Ireland

Thank you very much for your review and valuable comments on our manuscript. We have addressed these and provide point by point responses as below.

A clearly presented SWAT, including providing insight why carers do not participate in clinical trials

**Response:** Thank you

There are a number of limitations to this study, especially in phase 1. Findings from two carers are unlikely to have achieved data saturation calling into question using this information to develop a survey. It would be important to have more detail about the interview methods and how authors-maintained rigor.

**Response:** Yes, our interviews were unlikely to achieve data saturation or even sufficiency, which is why we additionally drew on the evidence from systematic reviews; we have emphasised this further by adding a sentence that we made a necessary pragmatic decision to use data from systematic reviews to inform the development of the survey in phase 2 due to the limited participation in the interviews (Design section, third paragraph, lines 1-2)

Recruitment from a national network was good, however, the fact that so few responded itself is problematic. Surveys are usually not well received; it would be helpful to know what other methods were used beyond mailing them.

**Response:** Other than a request to snowball, we didn't go beyond the Family Carers Ireland network in advertising our survey. We recognise, in hindsight, that this may have helped. We have added a sentence to the limitations section to this effect.

The discussion is too broad and goes beyond the data.

**Response:** The Discussion (in particular the implications section) and the Conclusion (including Abstract) sections has been amended (as per tracked changes) to address this point.

Likely this study needs to be replicated with a larger sample in both phase 1 and two.

**Response:** Thank you. We have noted this as a recommendation now (Conclusion section). We will plan for this opportunity as it might arise in a future trial.

Manuscript would benefit from revision.

**Response:** We have made revisions to the manuscript as per responses above.

**Competing Interests:** No competing interests were disclosed.

Reviewer Report 14 December 2020

<https://doi.org/10.21956/hrbopenres.14235.r28455>

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**Elizabeth Randell**

Centre for Trials Research, Cardiff University, Cardiff, UK

A clearly presented SWAT building on available data to provide insight into participation of informal care givers. This is a really interesting area on which to conduct this piece of research.

The authors have identified the limitations in the study design but I would add that the sample from phase 1 was very small. I would be wary of taking the findings purely from these 2 interviews forward to form the basis of the survey.

I think the manuscript could describe the content of the interview schedule briefly to inform the reader as to how this was devised.

Recruitment was from the Family Carers Ireland network - again, the authors have discussed this as a limited source of recruitment and perhaps this was a group of people already motivated the population in terms of making their voices heard. Did the authors consider how other carers might be reached? Collection and reporting of ethnicity data could also have been included as we consider how to reach under represented populations.

Further description could have been included with regards to any differences in motivators or challenges depending on the type of trial carers might take part in i.e. CTIMP versus non-CTIMP? The manuscript would benefit from having survey questions included.

I think that the results have been generalised to all carers too much and that there is important further research to be undertaken to examine how barriers faced might vary according to the needs of the individual being cared for e.g. issues around capacity and consent.

**Is the work clearly and accurately presented and does it cite the current literature?**

Yes

**Is the study design appropriate and is the work technically sound?**

Yes

**Are sufficient details of methods and analysis provided to allow replication by others?**

Partly

**If applicable, is the statistical analysis and its interpretation appropriate?**

Yes

**Are all the source data underlying the results available to ensure full reproducibility?**

Partly

**Are the conclusions drawn adequately supported by the results?**

Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Intellectual disability and autism

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

Author Response 07 Feb 2021

**Valerie Smith**, Trinity College Dublin, 24 D'Olier Street, Dublin, Ireland

Thank you very much for your review and valuable comments on our manuscript. We have addressed these and provide point by point responses as below.

A clearly presented SWAT building on available data to provide insight into participation of informal care givers. This is a really interesting area on which to conduct this piece of research.

**Response:** Thank you

The authors have identified the limitations in the study design, but I would add that the sample from phase 1 was very small. I would be wary of taking the findings purely from these 2 interviews forward to form the basis of the survey.

**Response:** Thank you; we have added a sentence to emphasise that we made a necessary pragmatic decision to use data from systematic reviews to inform the development of the survey in phase 2 (Design section, third paragraph, lines 1-2)

I think the manuscript could describe the content of the interview schedule briefly to inform the reader as to how this was devised.

**Response:** The interview schedule is available as an extended File; we have now inserted the link to this file in the text under the Phase 1 subsection of the Design section (available at: <http://www.doi.org/10.5281/zenodo.4029385>)

Recruitment was from the Family Carers Ireland network - again, the authors have discussed this as a limited source of recruitment and perhaps this was a group of people already motivated the population in terms of making their voices heard. Did the authors consider how other carers might be reached?

**Response:** Thank you, this is a really important point; we didn't go beyond Family Carers Ireland other than to request snowballing. We have added an additional sentence to the limitations section to address and clarify this.

Collection and reporting of ethnicity data could also have been included as we consider how to reach under-represented populations.

**Response:** Thank you; we did not collect ethnicity data, but certainly will consider this in any future SWAT-55.

Further description could have been included with regards to any differences in motivators or challenges depending on the type of trial carers might take part in i.e. CTIMP versus non-CTIMP? The manuscript would benefit from having survey questions included.

**Response:** We have added this important point as a recommendation for future research (as point below). The full survey document is available as an Extended File (with the access link provided in this section; <http://www.doi.org/10.5281/zenodo.4029385>)

I think that the results have been generalised to all carers too much and that there is important further research to be undertaken to examine how barriers faced might vary according to the needs of the individual being cared for e.g. issues around capacity and consent.

**Response:** We have edited the Discussion (in particular the implications section) and the Conclusion sections (including in the Abstract) to address this point. We have also included



the important point about the need for further research which would examine how barriers faced might vary according to the needs of the individual being cared for (Conclusion, last line).

***Competing Interests:*** No competing interests were disclosed.

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