# Views of healthcare professionals on recruiting to trials of psychosocial research: a qualitative study

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# Abstract

Background: Randomised controlled trials, and in particular those of psychosocial interventions, often fail to recruit to target, resulting in underpowered trials with poor generalisability of findings. The objectives of this study was to explore the views of healthcare professionals on recruiting to psychosocial research studies, and to explore their views on factors that may hinder or facilitate recruitment. Methods: We conducted 14 semi-structured interviews, with healthcare professionals who had been involved in recruitment into a randomised controlled trial of a talking therapy for depression in patients with advanced cancer. Interviews were transcribed and analysed using thematic analysis. Results: Six primary themes were identified, comprised of 15 subthemes. Attitudes towards research were largely positive. Health care professionals identified lack of time and narrow screening criteria as barriers to recruitment, and also noted the tendency to withhold participants from research for reasons other than eligibility (e.g., gatekeeping). The engagement of the study team with the clinical recruitment site, and the frequent presence of a researcher in clinics, were noted as facilitating recruitment. Conclusions: Healthcare professionals involved in recruiting to trials of psychosocial interventions hold generally positive views of psychosocial research, but report that constraints limit their ability to recruit. The findings from this study can inform how best to design trials, and in particular trials of psychosocial interventions, and train health care professionals for the study, to maximise recruitment. Trial registration: Controlled Trials ISRCTN07622709, registered 15 July 2011


# Background

Randomised controlled trials (RCTs) represent the gold standard for determining the clinical and cost effectiveness of health care interventions [1]. However, recruitment into RCTs often fails to meet targets: a review of trials funded by two UK bodies found less than a third reached their recruitment target, while half had to extend the recruitment period [2]. For example, one RCT of aromatherapy in advanced cancer found many patients were too ill to approach, a higher than anticipated number declined, and referrers acted as gate-keepers due to scepticism about treatment and the wish to reduce patient burden [3]. Failing to reach recruitment targets results in underpowered trials, with poor generalisability of findings [4].

Recruitment into trials in palliative care is beset by a unique set of problems [4] [5], including patients' disease burden, care providers being too busy, and "gatekeeping" by care providers. Gatekeeping refers to actions that control the provision of eligible patients [4]. Gatekeeping may be a problem in palliative care because of the desire to protect patients, and a reluctance to ask them to spend their remaining time participating in research [6]. A survey of healthcare professionals suggests this desire to protect end of life patients is widespread [7], and results in between 15% [7] and 24% [8] of palliative patients being excluded from research. However, this may be discordant with the wishes of palliative patients, who are generally happy to be invited to participate in research, experience direct and indirect benefits (such as feelings of altruism) from participation, and are averse to others saying "no" on their behalf [9].

Trials of psychosocial interventions in cancer patients have also been noted to face unique recruitment issues. Firstly, cancer patients may be preoccupied on treating the physical disease, and therefore may not make use of psychosocial services [3] [10]. Secondly, participants that do want support may feel deterred by the prospect of randomisation to a non-preferred group [3]. Given the difficulties faced in recruitment to palliative care trials and psychosocial RCTs, it is important to establish what barriers hinder recruitment, and explore potential methods of enhancing recruitment.

In this paper, we present qualitative findings from our experience of recruitment to the CanTalk study, a RCT comparing cognitive behavioural therapy (CBT) to usual care for treating depression in people with advanced cancer [11]. Despite successful overall recruitment, individual participating sites struggled with achieving recruitment targets, and expansion in number of sites and extension of the recruitment period were required. Our objective was to explore the views of those involved in recruitment into RCTs, what they perceive the barriers to recruitment to be, and what they think would facilitate increased recruitment.

# Methods

### Design

The study comprised qualitative interviews of healthcare professionals involved in recruiting to a RCT comparing Cognitive Behavioural Therapy with Treatment as Usual for depression in patients with advanced cancer, the CanTalk study [11].

Ethical approval was provided by the London – Camberwell St Giles NRES committee, reference 11/LO/0376. The study was supported by the National Cancer Research Network clinical trials portfolio.

### Participants, recruitment and setting

Participants were healthcare professionals (n = 14), selected through purposive sampling to include a range of clinical and research focused occupations, to reflect the range of occupations involved in recruitment to the CanTalk trial. Participants were recruited from the Christie NHS Foundation Trust, Barts Health NHS Trust, North Middlesex University Hospital, Weston General Hospital, Princess Royal University Hospital, South Tyneside NHS Foundation Trust, University College London Hospital, Whittington Health NHS Trust, and Marie Curie Hospice Hampstead.

### Topic guide

A topic guide (Table 1) was developed asking about 1) role in the oncology clinic; 2) previous research involvement; 3) views on trials other than clinical trials of investigative medicinal products (CTIMPs); 4) views about the CanTalk trial; 5) factors influencing recruitment; 6) feedback about the CanTalk trial; and 7) future research involvement. The guide was structured to begin with open questions to aid rapport, moving on to broad questions about research in general, before focusing on more specific questions about psychological research.

*Table 1 here.*

### Interviews

Interviews took place between December 2015 and March 2016. Informed consent was obtained prior to each interview. Interviews were conducted in a private room on the premises of the participants' place of work and lasted between 16 and 66 minutes. Interviews were recorded using a digital recording device. Interviews were conducted using a semi structured interview technique, based on the topic guide. This allowed for the interview to be directed by the topic guide, while also allowing for divergence from the guide to explore topics in greater depth or to explore issues raised by participants that were not specifically covered by the guide.

### Analysis

Recordings of interviews were transcribed verbatim. Data were analysed using thematic analysis based on commonly used guidelines [12], using Nvivo 11 software. We chose to use thematic analysis as it is not tied to any specific theoretical standpoint, and provides a flexible method that can be tailored to the research questions [12]. After familiarisation with the data, two researchers (TA and MA) independently coded the data and identified themes. These researchers then met to discuss the themes. Any differences were resolved through discussion. The analysis throughout, including the selection of text for coding and the search for themes, was guided by the study's research questions.

## Results

Of 50 healthcare professionals invited, 14 agreed to participate. All participants worked within the health care system and were involved in participant recruitment for the CanTalk study. Occupations and gender of participating healthcare professionals are provided in table 2.

*Table 2 here*

Six main themes emerged from the data: *1) Attitudes towards research; 2) Attitudes towards trials not of medicinal products; 3) Attitudes towards randomisation; 4) Views on study team vs in house researchers; 5) Factors limiting recruitment;* and *6) Factors facilitating recruitment*. From these, 15 subthemes were identified. A thematic map is provided in figure 1.

*Figure 1 here*

### Attitudes towards research

#### *Research helps build evidence base*

Several participants commented that research helps to *build up the evidence base* (HW12), *is the way forward* (HW03), and that randomised controlled trials are *the gold standard* (HW01)

*… according to the results it might help many more in future so it's like I'm being part of the future research evidence base that would be used probably five, ten years to come…* (HW05)

### *Research as part of remit*

A number of participants noted that research and recruitment are *part of my job* (HW05), or remit, for example:

*… most oncologists I know wouldn't feel like that cause they know that research is part of our work …* (HW14)

However one individual expressed the view that *I don't have dedicated time for research* (HW11) and another noted the added burden:

*…they're understaffed at the moment so they feel it's, research is like an added … it's added work for them …* (HW02)

## Attitudes to trials other than Clinical Trials of Investigative Medicinal Products (non-CTIMP trials)

### *Importance of trials not of medicinal products*

There was a commonly expressed theme that non-CTIMP trials are *very important* (HW11, HW12) and help meet patients' holistic needs:

*… I think if were looking at trying to, uh improve patient care from a kind of a holistic perspectives … these kind of studies and other similar ones are vital…* (HW08)

Some health care professionals also expressed the notion that both CTIMP and non-CTIMP trials hold equal importance, and recruitment centres *need a balance* (HW13):

*… we need to do both, 'cos we're paid for both (yeah) and we need to give patients the chance for both …* (HW02)

### *Advantages of trials not of medicinal products*

Several healthcare professionals noted advantages to non-CTIMP trials, such as being more *straightforward* (HW03), enabling them to spend *more time with* (HW01) and *chat with* (HW07) patients:

*… non-CTIMPs actually suit a hospital like the [name redacted] hospital very well, because they're not so resource intensive…* (HW01)

### *Bias towards trials of medicinal products*

Several healthcare professionals reported a bias towards recruiting for trials of medicinal products. Consultants were noted to *be involved more with CTIMP trials* (HW02), to be *just interested in medical*

*oncology really* (HW11), and to *favour their own studies* (HW01),

*… you only had one haematologist who'd think of CanTalk but the other would think about all the other CTIMP trials and then, you say, oh what about CanTalk, they're like, 'um, no, no, no' as in they push it to the back, that would be like the last resort …* (HW02)

This bias was accompanied by a perception that the *clinical trials points system gives more … funding point to trusts for … patients that are recruited into drug trials* (HW01):

*… they were probably told that we get more money for the CTIMP trials … so it's all I suppose funding …, so originally that's what it was, so that's what they would concentrate on, 'cos they need to bring more money to the Trust …* (HW02)

It was also noted that non-CTIMP trials could *get pushed* [out] (HW01), and that if there were treatment trials *patients will always get offered that first* (HW10):

*… I was pushing it saying yes we should take part, this is something we can do cause at the time there were very limited breast studies … but yes the time was um, perhaps a little frowned upon…* (HW03)

### Attitudes towards randomisation

#### *Always a fall-back*

Several healthcare professionals expressed the theme that randomisation to an intervention or usual care group was *no particular concern* (HW03) because the patient could *still get help if they needed it* (HW05):

*… it wasn't like if they were, if they were randomised to that and they didn't get any, the CBT it wasn't that they couldn't then have anything through the hospital …* (HW10)

#### *Randomisation necessary to answer question*.

Several healthcare professionals expressed that randomisation is necessary to answer the question, that it is *the only way that we can compare things* (HW10), provides a *scientifically robust test* (HW08), and is a *short term sacrifice for long term gain* (HW01):

*… though I've got patients at the moment who didn't get the active arm, perhaps I, I say to myself 'well in two years all of my patients will be getting this as standard treatment' …* (HW01)

#### *Randomisation difficult if allocated to treatment as usual*.

A number of healthcare professionals noted that it can be *difficult* (HW13) or *hard knowing that … patients aren't going to get what we really want them to get* (HW01). Healthcare professionals spoke of *worry* (HW12) and feeling *guilty* (HW10) about patients with depression being assigned to standard care:

*… it can be quite hard letting people know that they've not got the intervention and, if you know that people are you know really keen for it you can feel quite guilty*

… (HW10)

### Views on study team vs in house researchers

#### *Mixed views on advantages of UCL or in-house researchers recruiting for the study*

Views on staff from the university trial team conducting recruitment, as opposed to staff employed by the recruitment site, were mixed. Advantages of in-house clinical staff recruiting included the *advantage from us being actually embedded within [the clinic]* (HW13), having an established *relationship with a clinician* (HW13), and *sometimes they do it [participate] because they know you (HW3)*:

*…they know us well enough to know that we are not going to offer them something that they don't think might help…* (HW14)

Several healthcare professionals expressed advantages to researchers employed directly on the trial recruiting, noting that when trial researchers became involved it *felt like an enormous weight off* (HW03), that *we just wouldn't of had the resource* (HW04), and that UCL researchers were *more objective* (HW10) in selecting patients:

*… when your colleagues came from UCL the numbers went up again … because they looked, person, or this person is official and actually taken time to come from the University* … (HW02)

### Factors limiting recruitment

#### *Resource limitations*

Limitations in *time* (HW02) and *space* (HW10) were noted to limit recruitment. In terms of time, competing priorities (e.g. *always something more pressing to do*; HW03) and demands of a *two hour wait in clinic* (HW14) were noted. In terms of space, limited availability of *clinic rooms* (HW10) was noted as a limiting factor:

*… they were welcoming for us to come in a see the patients um, but again its busy clinics its clinic time its clinic rooms, its finding that space* … (HW10)

#### *Gatekeeping*

A number of healthcare professionals discussed pre-selecting patients. This included avoiding people *at the end of their life who are struggling* (HW03), who were *in a hospital bed and looking pretty sick* (HW03), and avoiding *people with really difficult personalities* (HW14). Reasons suggested for gatekeeping included not wanting *to upset their patients* (HW06) or to *give them any extra burden* (HW10):

*… you're not really going to be offering a therapy that they may not be around to benefit from …. and also put them to the inconvenience of going and sorting all this out …* (HW03)

Some Healthcare professionals displayed an awareness of their tendencies to gatekeep:

*… if you could be a bit more objective about it and think 'they meet the criteria I can go and speak to them', I think maybe sometimes it, it stopped us from approaching people …* (HW10)

One healthcare professional suggested that a researcher who is "*blind"* to the patients may be less likely to gatekeep:

*… sometimes coming in blind and not knowing all that information is fine because you can just discuss it with somebody and they can say yes or no…* (HW03)

### *Eligibility criteria too narrow*

Healthcare professionals noted that the catchment area restricted *what clinics we screened* (HW09) and constituted a *postcode lottery* (HW03). This theme also included the notion that the eligibility criteria were too narrow overall. *Broadening the patient eligibility* (HW08) criteria was noted as one factor that would increase recruitment.

… we had about eighty or ninety patients we had on that list, but then as these, like the barriers kept coming in we had to keep cutting out people …. so the list just kept going smaller … (HW02)

### *Patients do not want or need support*

This theme comprised the concept that many patients did not *need* (HW01) or *want* (HW08) support, including the rejection of *formalised* psychological support:

*…we had plenty of patients who both myself and the clinicians, like the consultants, really thought needed talking therapy because they would literally take up an hour of the medical oncologist's time but when it came to offering the study they didn't need any help ….* (HW01)

Some patients were noted to *choose church over study* (HW01). It was also noted that there may be less hopelessness among cancer patients and they *don't feel as hopeless now as they maybe did five or ten years ago* (HW07).

## Factors facilitating recruitment

### *Engagement*

It was deemed important for the trial to maximise *engagement* (HW12) with sites and *involve all the people* (HW03), including *oncologists* (HW12), *clinical trial coordinators* (HW12), *councillors* (HW03), and *clinical nurse specialists* (HW03). It was suggested that presenting the research at *pan London meetings*

(HW03) of nurse specialists or organisations such as the *London Cancer Alliance* (HW04) would be useful. Engaging regularly was deemed important, for example through *regular site visits* (HW01).

*… I think just engagement centrally umm you know keeping the clinicians who are involved in the trial up to date means not just it doesn't just mean having a newsletter …* (HW12)

***Presence of researcher***

The frequent *presence* (HW06, HW11) of a researcher, in *clinics* (HW14) and in *multi-disciplinary team meetings* (HW06, HW11), was noted as a key factor in facilitating recruitment. It was deemed useful to have *somebody there to catch all the patients that come into those clinics* (HW03), and to have a trial researcher who *forces themselves on the site* (HW01):

*… that's absolutely the key to recruitment, unless people jog us as clinicians regularly …. or sit and embed themselves in our meetings …. we are not going to be avid recruiters because there's so much else to think about…* (HW11)

# Discussion

Given the problems recruiting into RCTs, particularly within palliative care and trials of psychological interventions, it is important to explore why trials may under-recruit. The present study conducted qualitative interviews with health care professionals who had been involved in recruitment for a trial of a psychosocial intervention in an advanced cancer population. Overall, the study identified 6 main themes and 15 subthemes. Our findings suggest that whilst health care professionals felt that research was important, they did not have the time to engage in recruitment, and that trials of medicinal products were often prioritised over trials of psychosocial interventions.

Attitudes towards research in general were mainly positive, and healthcare professionals stated that psychosocial trials are worthwhile. However it was noted that research was extra work, and not part of their remit. Additionally, there was the notion that consultants prioritise trials of medicinal products. This bias towards trials of medicinal products, which are perceived to "count more" and provide more reward to the recruitment sites, may partly explain why trials of psychosocial interventions can be particularly problematic to recruit to [13].

Among factors influencing recruitment a primary theme was *resource limitations*, including time and space constraints and the competitive nature of recruitment. This theme is consistent with previous studies in which healthcare professionals stated that time is a factor limiting recruitment (e.g. [14] [15] [16]), and with palliative care research in which care providers stated they are too busy to provide patients with information about research [4].

Another barrier to recruitment is gatekeeping. Reasons that healthcare professionals in the present study gave for withholding patients included not referring patients who were too sick and not wanting to increase patient burden. Not wanting to increase the burden on palliative patients has emerged as a

reason for gatekeeping in several previous studies [7] [17] [18] [6]. The consequence is that these patients are denied the opportunity to participate. Indeed, what is viewed by health care professional as protecting a patient may be viewed differently by the patient, who are averse to others saying no on their behalf [9].

Narrow eligibility criteria was perceived as a key barrier, and has previously been noted as one of the main reasons for under recruitment into RCTs [19-21]. Indeed, researchers sometimes have to broaden the eligibility criteria in order to reach recruitment targets [e.g., 3]. Furthermore, healthcare professionals stated that those who are eligible often reject psychological support. This finding is consistent with previous research showing that patients declining to participate in trials of psychological interventions often feel they do not require a psychological intervention [3].

The theme *Engagement* is consistent with research demonstrating that receiving regular updates is useful [21]. Several trials have documented attempts to maximise engagement (e.g. [22]). Healthcare professionals in the present study also noted that the regular presence of the researcher in clinic and meetings maximised recruitment.

## Recommendations

Based on the present research, a number of recommendations can be made which should be considered during the design, set-up and running of clinical trials of psychosocial interventions, particularly those conducted within advanced cancer populations.

Firstly, during trial design, formulating a realistic estimation of the time that identification, screening, and referral of patients will take, and establishing weather healthcare professionals in referral sites will have dedicated time for these tasks, may help to ameliorate potential recruitment problems. This is particularly important given the competitive nature of recruitment, with multiple studies competing for staff time, and especially given that psychosocial research may be “pushed out” in favour of trials of medicinal products. Ring-fencing staff time dedicated to the study is required.

Secondly, educating staff involved in trial recruitment about the importance of RCTs may be beneficial to reducing gatekeeping. This could be done initially in set-up meetings. Providing information on the phenomena of gatekeeping, how the wish to protect patients is common among healthcare professionals [7] while being inconsistent with the views of palliative care patients [8], and possibly providing some quotes from the research literature of how palliative patients feel about being excluded from research, may be beneficial in reducing gatekeeping.

Thirdly, as recruitment is notoriously difficult within palliative care trials and trials of psychosocial interventions, it will be important during trial design to make the eligibility criteria as broad as possible. We suggest that it is good practice to carefully review each criteria to see if there is any way to broaden eligibility.

## Study Limitations

We approached 50 potential participants, out of whom 14 (28%) agreed to participate. There may be selection bias, and individuals who participated may have more positive attitudes towards psychosocial research. The interviewers, employed directly on the CanTalk trial, may also have had an influence on responses. Actively testing these recommendations, for example through the use of imbedded trials [23], is needed before we can be sure of the efficacy of any of these recommendations.

Notwithstanding these limitations, this study is the first to have investigated the views of health care professionals recruiting to a trial of a psychosocial intervention in an advanced cancer population. It has broadened our knowledge on factors facilitating and hindering recruitment into trials. The findings will hopefully facilitate recruitment into RCTs, and reduce the chance of these requiring extensions in time and costs.

### Conclusions

The views of those recruiting to randomised controlled trials provide insight into what may block or facilitate recruitment. Our findings suggest that whilst health care professionals felt that research was important, they did not have the time to engage in recruitment. Healthcare professionals also describe withholding participants from research (gatekeeping). Realistically estimating the time involved in recruitment and protecting or “ring-fencing” recruitment time, educating recruitment staff about the importance of RCTs, and keeping inclusion criteria as broad as possible are recommended. These findings can help inform those setting up randomised controlled trials to minimise potential hurdles.

# Declarations

### Declarations

### Ethics approval and consent to participate

Ethical approval was provided by the London – Camberwell St Giles NRES committee, reference 11/LO/0376. All participant’s provided written informed consent to participate.

### Consent for publication

Not applicable

### Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

### Competing interests

The authors declare that they have no competing interests

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### Author's contributions

TA conducted analysed the data, and wrote the manuscript. MA analysed the data, and helped write and comment on drafts of the manuscript. MS oversaw the research design and analysis, and helped write and comment on drafts of the manuscript. All authors read and approved the final manuscript.

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## List Of Abbreviations

CBT: Cognitive Behavioural Therapy

RCT: Randomised controlled trial

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# Tables

Table 1. Interview topic guide

| |
|---|
| 1. My first question will focus on you and your role in the oncology clinic. Describe your role in the oncology clinics. |
| · Can you describe your current role in this clinic to me? |
| · How did you come to be in this role? |
| · How do you feel about your role? |
| 2. My next question will look at your research participation to date. Have you been involved in any type of research in your role and can you tell me about it? |
| · What type of methodology? |
| · Duration of trial? |
| · Type of trial? |
| · Personal research or study (*phd, dissertation etc*)? |
| 3. I would like to ask you a little bit now on your views on trials that are not of medicinal products or drug trials. |
| · How often do you participate in this type of research? ( *For example psychological research, complex interventions and non CTIMPS (non drug trials*) |
| · To what extent do you feel these trials are part of your remit? |
| 4. I would like to ask you more specific questions now about your views on the CanTalk trial itself. |
| · What do you know about CanTalk study? |
| · (*Preamble: as you are aware the CanTalk trial was conducted by researchers from UCL)* What are your views about the research being carried out by the university and not embedded in the clinic team? |
| · What are your views on CanTalks' comparison of active treatment compared with usual care (*for example randomised trials*)? |
| 5. Now I will ask you questions about your participation in the CanTalk trial. |
| · How do you think your feelings about research influence involvement? |
| · How do both, your patient's reactions to research and experiences of participation, affect your involvement in the research? |
| · What factors do you think may influence recruitment? (Prompts – anything that might increase recruitment? Factors influencing poor recruitment?) |
| 6. I would like to ask you now to tell me about any patient feedback you have had about CanTalk. |
| · Have any of your patients' mentioned the trial? (*prompt positive or negative responses*) |
| · How do you feel the trial affected your patients? |
| 7. Lastly I would like to ask you about your opinions on psychological research studies like this in the |

future. Would you participate in this type of research in the future?

· Why do you say this?

· (*Depending on response, if negative*) What might make you invest more in these types of trials? (*prompt: more CPD points, professional development or topic you are passionate about*)

8. Overall what did you think about the CanTalk study and do you have any suggestions for improvements to CanTalk and studies like these in the future?

Table 2. Participant demographic data

| Identifier | Roll |
|---|---|
| HCP01 | Clinical Research Practitioner |
| HCP02 | Research Nurse |
| HCP03 | Clinical Nurse Specialist |
| HCP04 | Consultant Clinical Psychologist |
| HCP05 | Clinical Nurse Specialist |
| HCP06 | Staff Doctor |
| HCP07 | Clinical Trials Officer |
| HCP08 | Oncology Consultant |
| HCP09 | Research Nurse |
| HCP10 | Research Nurse |
| HCP11 | Palliative Care Consultant |
| HCP12 | Oncology Consultant |
| HCP13 | Research Nurse |
| HCP14 | Oncology Consultant |

# Figures

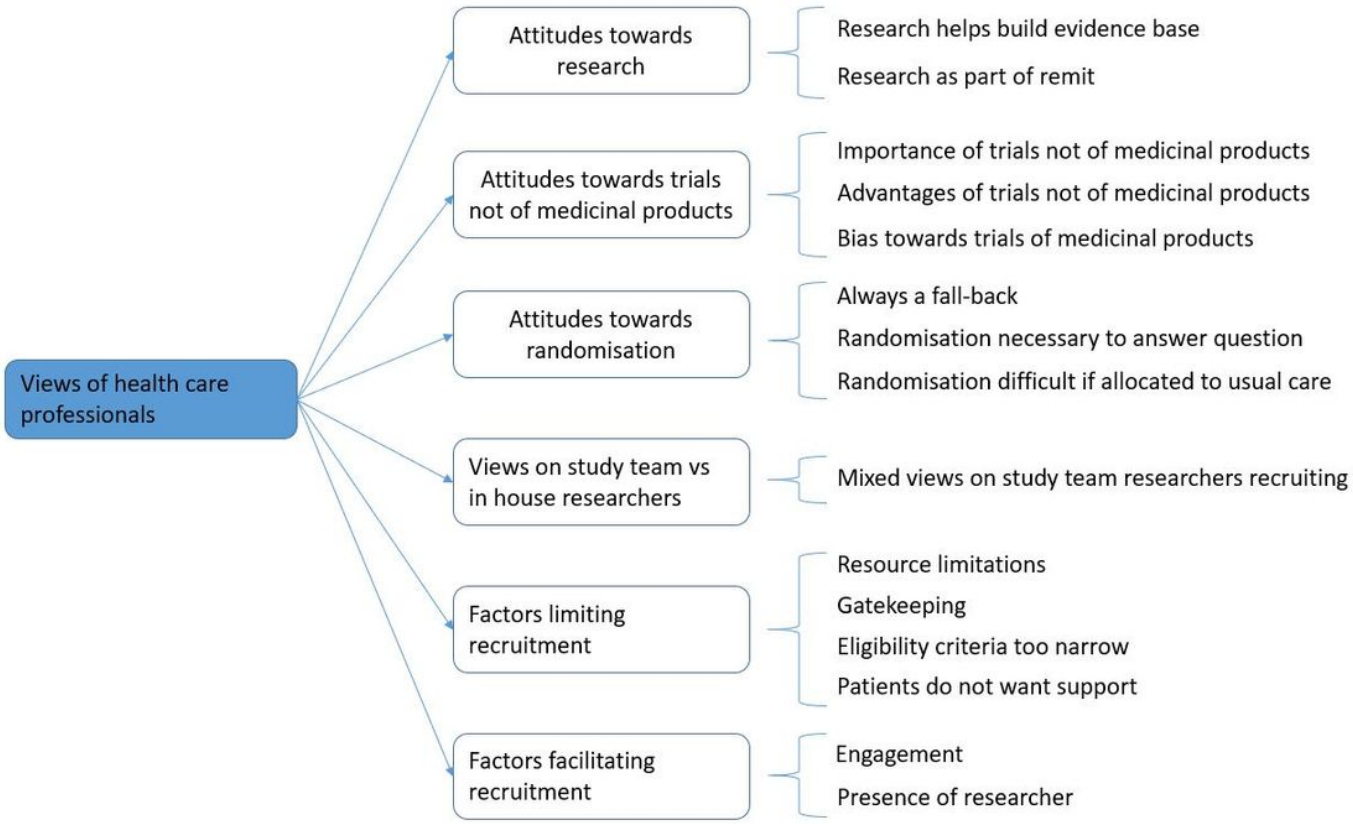


**Figure 1**

Thematic map of data

# Supplementary Files

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- supplement1.docx