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## Non-participants and reasons for non-participation in a pragmatic trial of energy healing as cancer rehabilitation

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**Title:** Non-participants and reasons for non-participation in a pragmatic trial of energy healing as cancer rehabilitation

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**Abstract**

*Background:* The problems associated with clinical trial participation have been highlighted in the literature, but few studies have examined why patients decline to participate.

*Aims:* To describe non-participants' and participants' characteristics and examine reasons for non-participation in a pragmatic trial of energy healing for rehabilitation for colorectal cancer.

*Methods:* Three to seven days after postal recruitment, all eligible participants (n=783) were contacted by telephone. Reasons given for non-participation were recorded in 5 categories. Data were analysed using Chi<sup>2</sup>.

*Results:* More men than women declined to participate (men= 55.7%; women= 44.3%; p=0.022). Non-participants were on average older than participants (non-participants: mean age 68.4; SD (9); participants: mean age 64; SD (8.8); p<0.001), and had only received surgery (non-participants = 54.1%; participants= 40.1%; p<0.001). The most frequent reasons for non-participation were 1) No need for rehabilitation (n=81; 28.6%) 2) Participation too burdensome (n= 67; 23.7%) 3) No interest in energy healing (n=57; 20.1%). If the time span between study recruitment and surgery was 0-9 months, participation was frequently considered too burdensome (p=0.020), especially by women (n=45; 67.2%; p=0.001) and those aged ≥ 68 (n=54; 80.6%; p= 0.013); rehabilitation was frequently considered not needed 10-17 months after surgery (p=0.035).

*Conclusion:* Non-participation in a trial of energy healing as rehabilitation for colorectal cancer revealed an interplay between non-participants' demographic characteristics, health experiences, everyday life priorities and the offered rehabilitation intervention. To optimize recruitment to studies of cancer rehabilitation, consideration of disease trajectories and potential participants' rehabilitation needs is suggested.

**Key words**

Pragmatic trial; trial non-participation; trial participation; cancer rehabilitation; complementary and alternative medicine; energy healing

## Background

In 2006, colorectal cancer was estimated to be the second most common form of cancer diagnosed in Europe and the second most common form of death from cancer [1]. Diagnosis and treatment of colorectal cancer has significant impact on people's lives. People with colorectal cancer experience poor quality of life following surgery and treatment [2], and continue to experience side-effects after treatment [3-5]. Colorectal cancer-related symptoms include fatigue, digestive problems, memory lapses, sexual problems, lack of concentration, and sleep interruptions [5]. These and other symptoms may make daily activities difficult [6, 7].

Complementary alternative medicine (CAM) is widely used by cancer patients [8-11], including in colorectal cancer [12], and is commonly combined with biomedical treatment [13-16]. Amongst cancer patients, energy healing is one of the ten most chosen therapies for CAM cancer care in Europe [16] and used by up to 10% of cancer patients in Denmark [14].

In 2011-12, a pragmatic trial on energy healing as rehabilitation for colorectal cancer was conducted in Denmark in order to test guidelines for effectiveness studies measuring personalized goals of treatments [17-20]. Considerable efforts were made to enlist participants for the trial, based on strategies to increase trial participation examined in the literature [e.g. 21, 22, 23], such as the inclusion of a pre-paid envelope and follow-up contact by telephone. Despite these efforts, only 31.5% of eligible participants responded. The aim of this article is to contrast non-participants' and participants' characteristics and examine non-participants' reasons for declining to take part in the trial. Although the problems associated with trial participation have been highlighted in the literature [e.g. 24, 25, 26], few studies have examined why patients refuse to participate in clinical trials [24]. This article provides insights into motivations and reasons that underpin non-participation in a pragmatic trial of energy healing as cancer rehabilitation.

## Methods

### Recruitment of patient participants

Based on an extraction from the Danish National Patient Registry a total of 783 persons were considered eligible to participate in the trial. Eligibility criteria included: 1) primary diagnosis of colorectal cancer, defined as C18- C20, according to the International Classification of Diseases (ICD10) 2) treated with surgery or surgery combined with chemotherapy and/or radiotherapy in the Southern or Central Region of Denmark between 1 March 2010, and 1 August 2011, and without evidence of current cancer; and 3) aged  $\leq 80$  at study inclusion. Patients were excluded if they: 1) were unable to comply with the data collection protocol, 2) had poor understanding of the Danish language, or 3) were receiving palliative care or had a recurrence of cancer prior to inclusion.

Using a centralized, computerized procedure, Minim (Minimization Program for Allocating Patients to Treatments in Clinical Trials), eligible participants were randomly stratified according to gender into a self-selection arm or a randomization arm prior to initial contact. This randomization design, based on energy healing versus no treatment, was chosen because of the primary hypothesis that patients who self-select the energy healing intervention will experience greater effects for primary outcomes than patients who are randomized to the intervention. This design also makes it possible to examine whether there might be a relationship between trial participation or non-participation and allocation to randomization or self-selection arms.

Eligible participants were mailed a folder containing: written information about the study; a leaflet containing information about the healers in the study; an informed consent form; a pre-paid envelope; and the first part of a questionnaire package. The accompanying letter differed, depending whether recipients were allocated to the self-selection arm or the randomization arm. Recipients in the self-selection arm were informed that they could choose between treatments with energy

healing and allocation to the control group. Recipients in the randomization arm were informed that they would be allocated either to receive energy healing or to be in the control group. Participants not receiving the energy healing intervention during the trial were offered one free treatment with an energy healer after trial completion; this was taken up by one participant only (for details of recruitment and randomization, see Figure 1).

Insert Figure 1 about here

Three to seven days after the mailed invitation, two research assistants made telephone calls to all eligible participants (n=783) in order to answer any possible questions concerning the study, exclude potential participants who did not fulfill the inclusion criteria (such as known recurrence of cancer), and to ask for possible reasons if participation was declined. Questions such as 'do you have a particular reason for not wanting to participate?' and 'why do you not want to participate in this trial' guided the elicitation of reasons for non-participation, if no reasons had been forthcoming during the earlier part of the conversation. The elicited primary reason (one reason per person only), was immediately recorded in a non-participation log, according to six topics: 1) does not wish to participate in a trial of CAM or energy healing, 2) does not have the vitality, strength or energy to participate in such an extensive trial, 3) does not wish to use time on any trial participation, 4) does not like to be in randomization arm of trial, 5) rehabilitation not relevant, as the respondent is well and does not want to focus on illness any longer 6) cannot complete questionnaires, find transport, and similar. These six topics derived from engagement with literature about trial participation [for example, 21-23, 24, 26] and the interest to establish whether the therapy of energy healing impacted on non-participation.

If an eligible participant had not returned the questionnaire within 2-4 weeks a reminder call was made, following the same above procedure; hereafter no-response was considered non-participation. A total of 247 individuals participated in the study (response rate 31.5%; men n=115, 46.6%; women n=132, 53.4%).

### Intervention procedure

The intervention consisted of four sessions of energy healing spread over a 2-months period; the distribution of sessions was decided by each participant-healer<sup>1</sup> pair. Patient participants chose one of the participating healers, and the energy healing sessions took place at the healers' clinic. The energy healing delivered was not restricted to a specific form of energy healing, provided that it was based on the general idea of the healer transmitting some kind of "energy" to the participant. Conversation "as usual" was accepted, but no other form of therapy than energy healing was allowed.

### Datasets

All participants were asked to complete questionnaires at five points during the study (see Figure 2): at inclusion (T1); ten days after inclusion and before the start of treatment (T2 - baseline); 4-6 weeks after baseline (T3, in connection with the third treatment for those who received energy healing); 8 weeks after baseline (T4, after the last treatment); and 16 weeks after baseline (T5, two months post-treatment). Questionnaires included the Measure Yourself Concern and Wellbeing questionnaire (MYCaW) and a range of standardized validated questionnaires on, for example, quality of life, mood, sleep and depression. Further, all participants were asked to choose the most important area of concern on a priority list presenting seven overarching categories of concerns that were covered by the validated questionnaires: cancer related symptoms (including late effects of cancer treatment), physical activity, quality of life, depressive symptoms, mood, sleep quality, economy. A further option, 'other concerns', was included in the priority list.

Four qualitative semi-structured interviews lasting on average one hour

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<sup>1</sup> Healers were identified and recruited through a national association of healers ('Healer-Ringen'). Additional inclusion criteria were: 1) treatment facilities used solely for the practice of healing, and 2) clinic location within the regions of Central and Southern Denmark. A total of 31 healers were included.



were conducted at T2, T3, T4 and T5 with 32 participants selected strategically to cover a range of ages, occupations, living conditions and prior experience with complementary and alternative medicine; one participant dropped out after the first interview, reducing the sample to 31 participants. The first and last interviews were conducted in the participants' homes, and the second and third interviews were carried out by telephone or Skype. Furthermore, at T2, T4 and T5, 65 participants completed a diary in which they recorded their daily activities on an hourly basis over five days.

Insert Figure 2 about here

### Ethics

The study adhered to the ethical requirements of the Helsinki Declaration. Participants received written and oral information about the study, and were informed that they were free to withdraw from the study at any time during the study period. The study was presented to the regional Committee of Research Ethics in Southern Denmark; the Committee decided that the study did not require their approval. The study has been approved by the Danish Data Protection Agency.

### Analysis of non-participant log

Responses were analysed and the following categories established:

- 1) No need for rehabilitation (based on expressions of being well and/or having physically, emotionally and mentally adapted to the cancer experience)
- 2) Study participation physically, emotionally and/or mentally too burdensome (based on expressions of wanting to attend to issues related to the cancer experience, other health-related concerns or everyday life priorities)
- 3) No interest in energy healing, for example as a form of therapy in rehabilitation
- 4) No time for study participation (based on expressions of being busy with professional and social engagements and commitments)
- 5) Other (for example, not wanting to participate in any research; feeling too old; dissatisfaction with allocation to randomization arm [one response only])

After contact with the first 50 potential participants, these categories were reassessed and confirmed as useful after slight modifications.

### Statistical analysis

All data were analysed using the Statistical Package for Social Sciences (SPSS), version 19. Descriptive statistics were calculated with all variables to summarise the data. Differences in socio-demographic characteristics between the different populations were assessed using the Chi<sup>2</sup> test.

### **Results**

The eligible recruitment population (n=783) comprised 52.6% men (n= 412) and 47.4% women (n= 371), aged 29-80 (mean age 66.9); 94 (12%) eligible participants were excluded. At the end of the recruitment period 56.5% (n=442) of the eligible recruitment population were considered non-participants, resulting in a non-participation rate of 68.5% (see Figure 3).

Insert Figure 3 about here

### Non-participants' characteristics

Of the non-participants, 55.7% (n=246) were men and 44.3% (n=196) were women. Mean age was 68.4 (age 29-80), with a majority (n=272) aged  $\geq 68$ ; men and women were distributed nearly equally between those aged  $\leq 67$  and those aged  $\geq 68$  ( $X^2$ (df 1)=1.579; p=0.209). The majority of non-participants (n=239; 54.1%) had undergone surgery only (see Table 1).

Insert Table 1 about here

### Participants' characteristics

Of the participants, 53.4% (n=132) were women and 46.6% (n=115) were men. Mean age was 64 (age 36-80), with near equal distribution of those aged  $\leq 64$  and those aged  $\geq 65$ ; more women (n=76; 30.8%) were in the younger age group and more men (n=71; 28.7%) in the older age group ( $X^2$ (df 1)=9.178;p=0.002). The majority of

participants (n=148; 59.9%) had received chemotherapy and/or radiotherapy in addition to surgery (see Table 1).

#### Comparison between non-participants' and participants' characteristics

Amongst the non-participants were slightly more men than women (men: n=246, 55.7%; women: n=196, 44.3%), compared to the study participants (men: n=115, 46.6 %; women: n=132, 53.4%; p=0.022). The mean age of non-participants was 68.4, compared to participants' mean age of 64, making the non-participants overall older than participants (p<0.001). More than half of the non-participants had received only surgery, while more than half of participants had received chemotherapy and/or radiotherapy in addition to surgery (p<0.001). Accordingly, non-participants were more likely to be men who had only received surgery, with a mean age of 68.4. No further differences concerning study recruitment since surgery (p=0.909) or distribution to randomisation or self-selection arms (p=0.175) can be detected (see Table 1).

#### Reasons for non-participation:

Reasons to decline study participation are known for 64% (n=283) of non-participants (see Figure 3); 20.1% (n=89) eligible participants who had not responded to the invitation letter could not be contacted by telephone; 15.8% (n=70) had been contacted but were undecided at the time and in the event did not participate and their reasons for non-participation are unknown. It is the 283 non-participants' primary reasons not to take part in the study that are examined here.

This sample of non-participants is characterised by near equal gender distribution (women n=138; men 145), with 68.2% (n=193) aged  $\geq 68$ ; 55.1% (n=156) had received only surgery with near equal division across the time spans since surgery; 53% (n=150) were in the randomisation arm (see Table 2).

The most frequently given primary reason for non-participation was that there was 'no need for rehabilitation' (n=81, 28.6%), followed by the perception that study participation would be 'too burdensome' (n=67, 23.7%) and 'no interest in energy healing' (20.1%, n=57) (see Table 2). In particular, women and those aged  $\geq 68$  conveyed that study participation was too burdensome (n=45, 67.2%,  $p=0.001$ ; n=54, 80.6%,  $p=0.013$  respectively), and the majority who expressed a lack of interest in energy healing were men (n=35, 61.4%,  $p=0.086$ ). Furthermore, particularly men (n=10; 71.4%;  $p=0.121$ ) and those aged  $\leq 67$  (n=9; 64.3%;  $p=0.007$ ) mentioned not to have time for participation (see Table 2). Table 2 also indicates that no significant differences were found with regard to distribution into randomisation or self-selection arms, although 78.6% (n=11,  $p=0.049$ ) of non-participants who expressed to not have time for participation were in the randomisation arm.

Insert Table 2 about here

As Figure 4 indicates, there appears to be a relationship between the time span since cancer surgery and recruitment to the trial on the one hand, and the categories 'participation too burdensome' and 'no need for rehabilitation' on the other. If recruitment took place 0-9 months since surgery, invitation to the trial frequently seemed to be perceived as 'too burdensome' ( $X^2(df 3)=9.851$ ,  $p=0.020$ , Cramer's  $V=0.187$ ), especially by women (n=45; 67.2%;  $p=0.001$ ) and those aged  $\geq 68$  (n=54; 80.6%;  $p=0.013$ ). By contrast, if recruitment took place 10-17 months since surgery, participation in the trial frequently seemed to be 'not needed' ( $X^2(df 3)=8.626$ ,  $p=0.035$ , Cramer's  $V=0.175$ ). Time span since surgery did not seem to have implications concerning the other categories.

Insert Figure 4 about here

## Discussion

This article described the characteristics of non-participants and participants in a pragmatic trial of energy healing as rehabilitation in colorectal cancer, and examined

reasons for non-participation. Findings indicate that in our sample of non-participants (n=422), non-participants were more likely to be men (n=246, 55.7%) with a mean age of 68.4 who had only received surgery. By contrast, participants were more likely to be women (53.4%; n=132), with a mean age of 64, and had received chemotherapy and/or radiotherapy in addition to surgery (n=148; 59.9%).

Based on semi-structured telephone interviews, this article also investigated individuals' reasons for non-participation. The exploration of non-participants' primary reasons to decline participation in a trial of energy healing as rehabilitation for colorectal cancer reveals a complex interplay between gender, age, time span since completion of cancer-related treatment, health and other needs and priorities, and the status of energy healing for cancer care. The most frequent primary reason (28.6%) for non-participation given by respondents was that they had no need for rehabilitation, indicating that they were well and/or had adapted physically, emotionally and mentally to their cancer experience. This can be seen in light of the trial inclusion criteria, which recruited participants who had completed cancer-related hospital treatment within the past 18 months prior to study inclusion. On the other hand, 23.7% of non-participants, particularly women and those aged  $\geq 68$ , considered participation as too burdensome, given their cancer-related and/or overall health needs and priorities concerning their everyday lives. This might imply that the extent of poor quality of life and/or side effects experienced as a result of colorectal cancer and its treatment [2-5] may continue to have significant limiting impact on these respondents' everyday life [6, 7], leading to decline participation in research. Practical issues relating to trial participation, and the commitment required in terms of time and effort may also lead to participation being perceived as a burden [24, 26, 27]. In addition, 80.6% of those perceiving participation as too burdensome where aged  $\geq 68$ ; this may confirm the tendency that CAM use in Denmark decreases with age [28].

A significant number of respondents (20.1%), particularly men (61.4%), declined participation due to a lack of interest in energy healing as a form of rehabilitation. This reflects the general trend that more women than men use CAM [13], including

for cancer in Denmark [14, 28]. Furthermore, while energy healing is among the most frequently used therapies for CAM cancer care in Europe [16] and one of the most used forms of CAM in Denmark [29] only 7% of the Danish population have ever used this therapy [29], and up to 10% of cancer patients use it in cancer care [14]. This relatively low interest in energy healing for cancer is therefore also reflected in our finding of limited interest in energy healing for rehabilitation in colorectal cancer; it also confirms Richardson et al's [26] finding that 24.3% of women respondents lacked interest to participate in a trial of CAM after breast cancer. Lastly, in our study particularly men and those aged  $\leq 67$  (4.9%) mentioned the lack of time for research participation, pointing to the possibility that male and/or younger respondents may have taken up professional and/or social commitments again following the completion of cancer-related hospital treatment. In sum, non-participation in clinical trials is a complex phenomenon that is grounded in an interplay between non-participants' demographic characteristics, health experiences, everyday life priorities and the offered rehabilitation intervention.

Identifying the most suitable time to recruit trial participants in investigations of rehabilitation interventions is critical. Our findings highlight that in the earlier months (months 0-9) following completion of treatment for colorectal cancer trial participation may be considered to be 'too burdensome', while immediately after treatment completion (months 0-5), cancer rehabilitation may possibly be perceived as 'not yet needed'. On the other hand, study recruitment after a longer time span since treatment (months 10-17), and accommodations possibly to have been made to the cancer experience and cancer-related symptoms, rehabilitation interventions may perhaps be perceived as 'not needed *any longer*' or also as 'too burdensome' to be fitted into everyday life commitments and routines. These findings point to the importance of considering study recruitment in the contexts of disease trajectories and potential participants' rehabilitation needs [30], as well as the general barriers and facilitators of clinical trial recruitment, such as demands on time, work schedules, transport and childcare issues, and the wish to forget illness experiences [24-26].

Inevitably, there are limitations to this study. Although an investigation of non-participation was intended from the inception of the trial, it constituted only a small sub-study. Therefore, only selected factors known to influence trial participation and non-participation were explored when asking potential participants about their reasons for non-participation. Further, the study of non-participation presented here was part of a complex cross-disciplinary trial that called for extensive input and time-consuming commitments from trial participants over a lengthy period of time. This may be reflected in the high number of responses that perceived participation to be too burdensome. Lastly, for purposes of comparison it would have been relevant to also investigate participants' reasons for participation in the trial.

### **Conclusion**

The exploration of non-participants' characteristics and reasons for non-participation in a pragmatic trial of energy healing as rehabilitation in colorectal cancer demonstrates an interplay between demographic characteristics, health experiences and needs, everyday life priorities and the offered rehabilitation intervention. More men than women declined participation; non-participants were on average older than participants and had received only surgery. Participation was frequently declined on the grounds of trial participation being too burdensome (especially 0-9 months after surgery), rehabilitation not being needed (especially 10-17 months after surgery), and a lack of interest in energy healing. To optimize recruitment to trials of cancer rehabilitation, consideration of disease trajectories and potential participants' rehabilitation needs, together with general barriers and facilitators of trial participation is suggested.

### **Conflict of interest**

None to declare

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Table 1: Non-participant and participant characteristics

	Non-participants N=442 N(%)	Participants N=247 N(%)	p value
<b>Gender:</b>			$\chi^2(df1)=5.258$ <b>p=0.022<sup>a</sup></b>
Women	196 (44.3)	132 (53.4)	
Men	246 (55.7)	115 (46.6)	
<b>Age:</b>	Range [29-80] Mean 68.42; SD [8.998]	Range [36-80] Mean 64.06; SD [8.842]	$\chi^2(df1)=31.586$ <b>p&lt;0.001<sup>a</sup></b>
≤ 67 years	170 (38.7)	150 (60.7)	
≥ 68 years	272 (61.5)	97 (39.3)	
<b>Cancer treatment:</b>	Range [0-115; numbers of chemo/radio treatments] Mean 11.07; SD [19.775]	Range [0-116; numbers of chemo/radio treatments] Mean 14.02; SD [21.857]	$\chi^2(df1)=12.412$ <b>p&lt;0.001<sup>a</sup></b>
Surgery	239 (54.1)	99 (40.1)	
Surgery + chemo/radio	203 (45.9)	148 (59.9)	
<b>Months since Surgery:</b>			$\chi^2(df3)=0.544$ p=0.909 Cramers value=0.028
0-5 months	107 (24.2)	54 (21.9)	
6-9 months	106 (24.0)	61 (24.7)	
10-13 months	115 (26.0)	68 (27.5)	
14-17 months	114 (25.8)	64 (25.9)	
<b>Randomisation/ Self-selection:</b>			$\chi^2(df1)=1.837$ p=0.175
Randomisation	226 (51.1)	113 (45.7)	
Self-selection	216 (48.9)	134 (54.3)	

<sup>a</sup> significant p value in bold

Table 2: Primary reasons for non-participation (n=283)

	<b>All primary reasons<sup>a</sup></b> N=283 (100%) N (%)	<b>No need for rehabilitation<sup>b</sup></b> N=81(28.6% of n=283) N (%)	<b>Participation too burdensome<sup>b</sup></b> N=67(23.7% of n=283) N (%)	<b>No interest in energy healing<sup>b</sup></b> N=57(20.1% of n=283) N (%)	<b>No time for participation<sup>b</sup></b> N=14(4.9% of n=283) N (%)
<b>Gender:</b>					
Women	138 (48.8)	42 (51.9)	45 (67.2)	22 (38.6)	4 (28.6)
Men	145 (51.2)	39 (48.1)	22 (32.8)	35 (61.4)	10 (71.4)
<i>P value</i>	$X^2(df4)=16.442$ <b><math>p=0.002^c</math></b>	$X^2(df1)=0.433$ $p=0.510$	$X^2(df1)=11.896$ <b><math>p=0.001</math></b>	$X^2(df1)=2.953$ $p=0.086$	$X^2(df1)=2.487$ $p=0.121$
<b>Age:</b>					
≤ 67 years	90 (31.8)	23 (28.4)	13 (19.4)	23 (40.4)	9 (64.3)
≥ 68 years	193 (68.2)	58 (71.6)	54 (80.6)	34 (59.6)	5 (35.7)
<i>P value</i>	$X^2(df4)=14.110$ <b><math>p=0.007</math></b> CV <sup>d</sup> =0.223	$X^2(df1)=0.607$ $p=0.436$	$X^2(df1)=6.222$ <b><math>p=0.013</math></b>	$X^2(df1)=2.405$ $p=0.121$	$X^2(df1)=7.166$ <b><math>p=0.007</math></b>
<b>Cancer treatment:</b>					
Surgery	156 (55.1)	47 (58)	38 (56.7)	31 (54.4)	4 (28.6)
Surgery + chemo/radio	127 (44.9)	34 (42)	29 (43.3)	26 (45.6)	10 (71.4)
<i>P value</i>	$X^2(df4)=4.380$ $p=0.357$ CV=0.124	$X^2(df1)=0.386$ $p=0.534$	$X^2(df1)=0.090$ $p=0.764$	$X^2(df1)=0.016$ $p=0.900$	$X^2(df1)=4.198$ <b><math>p=0.040</math></b>
<b>Months since Surgery:</b>					
17-14 months	73 (25.8)	25 (30.9)	15 (22.4)	10 (17.5)	3 (21.4)
13-10 months	72 (25.4)	25 (30.9)	9 (13.4)	19 (33.3)	4 (28.6)
9-6 months	67 (23.7)	10 (12.3)	22 (32.8)	11 (19.3)	4 (28.6)
5-0 months	72 (25.1)	21 (25.9)	21 (31.3)	17 (29.8)	3 (21.4)
<i>P value</i>	$X^2(df12)=23.412$ <b><math>p=0.024</math></b> CV=0.166	$X^2(df3)=8.626$ <b><math>p=0.035</math></b> CV=0.175	$X^2(df3)=9.851$ <b><math>p=0.020</math></b> CV=0.187	$X^2(df3)=4.847$ $p=0.183$ CV=0.131	$X^2(df3)=0.016$ $p=0.900$ CV=0.037
<b>Randomisation/ Self-selection:</b>					
Randomisation	150 (53.0)	42 (51.9)	35 (52.2)	33 (57.9)	11 (78.6)
Self-selection	133 (47.0)	39 (48.1)	32 (47.8)	24 (42.1)	4 (21.4)
<i>P value</i>	$c X^2(df4)=5.800$ $p=0.215$ CV=0.143	$X^2(df1)=0.060$ $p=0.806$	$X^2(df1)=0.021$ $p=0.886$	$X^2(df1)=0.686$ $p=0.408$	$X^2(df1)=3.865$ <b><math>p=0.049</math></b>

<sup>a</sup> Chi<sup>2</sup>-statistics comparing the primary reasons for non-participation with gender, age, cancer treatment, months since surgery, and randomization/self-selection.

<sup>b</sup> Chi<sup>2</sup>-statistics comparing the primary reason for non-participation with gender, age, cancer treatment, months since surgery, and randomization/self-selection.

<sup>c</sup> Significant p value in bold

<sup>d</sup> Cramer's value

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Figure 1: Patient recruitment and randomization

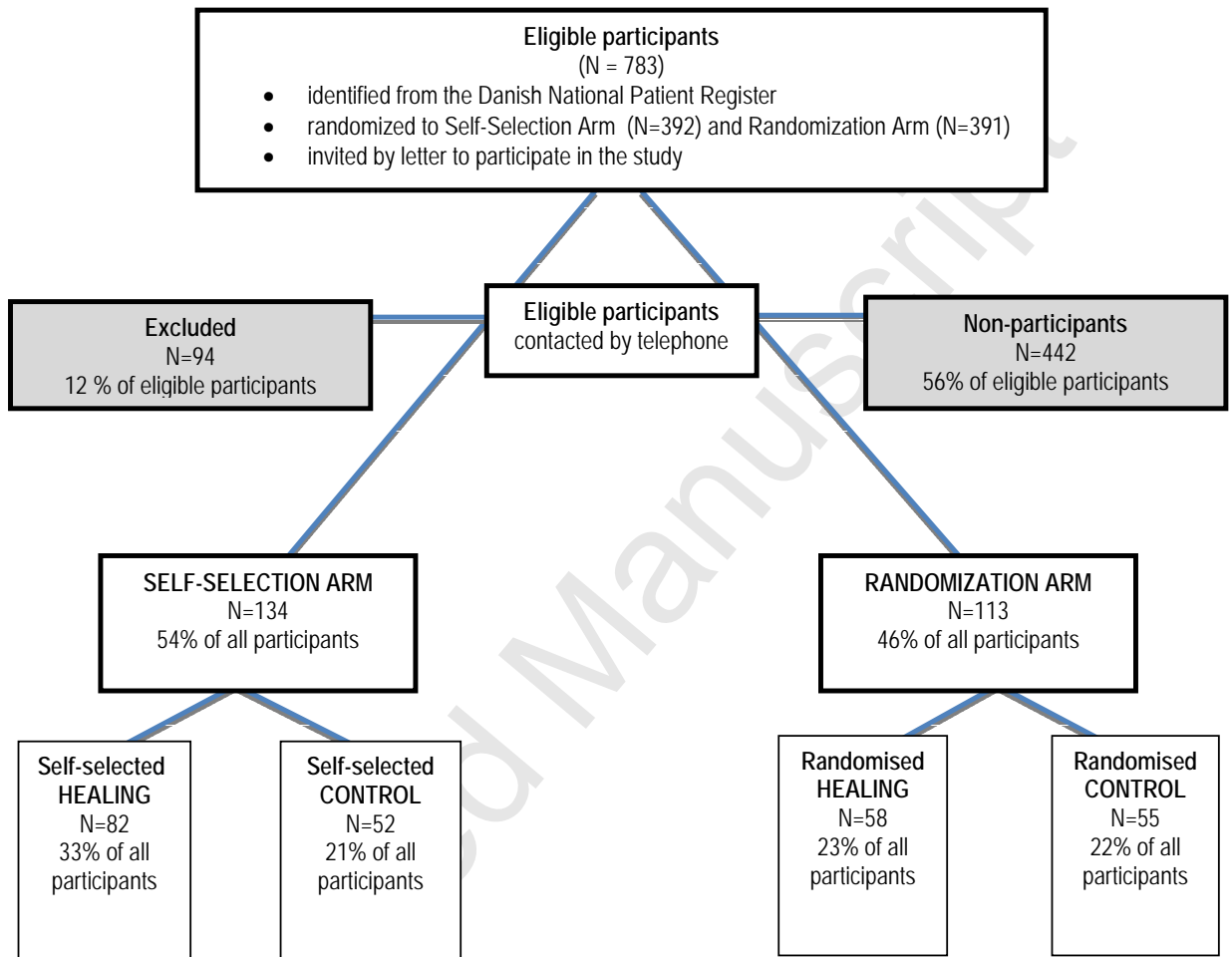


Figure 2: Time line

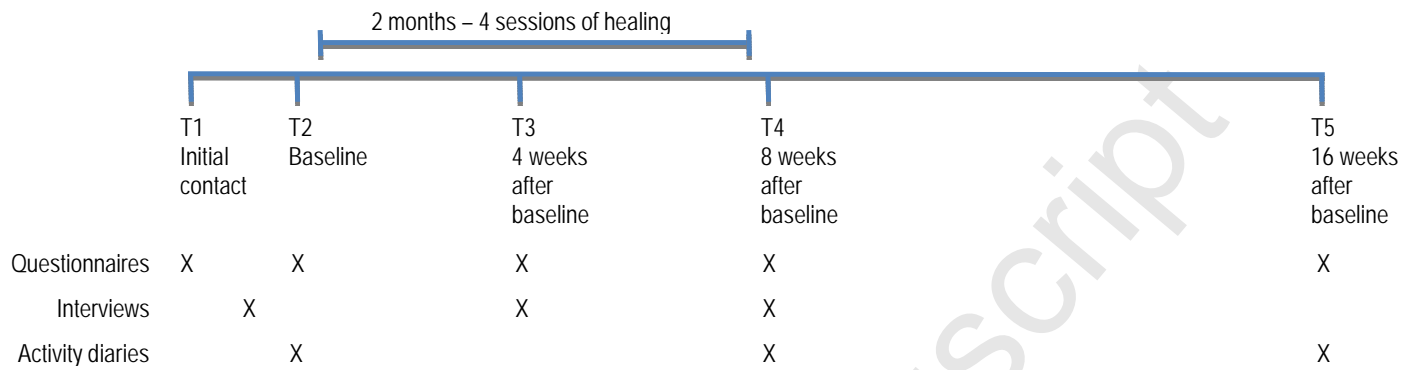


Figure 3: Non-participation and reasons for non-participation

