Process evaluation of the PREPARE trial

Preoperative inspiratory muscle training to prevent postoperative pneumonia in patients undergoing esophageal resection

Master Thesis

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bevestigt hierbij dat de onderhavige verhandeling mag worden geraadpleegd en vrij mag worden gefotokopieerd. Bij het citeren moet steeds de titel en de auteur van de verhandeling worden vermeld."

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SAMENVATTING

Doelstelling: Slokdarmkanker is een veel voorkomende ziekte met een groeiende incidentie. Chirurgische resectie van slokdarmkanker is de meest voorkomende behandeling bij slokdarmkanker. Na operatie is het overlijdensrisico na optreden van een longontsteking 20%, tegen 3% zonder longontsteking. De PREPARE studie (preoperatieve ademspiertraining om longontsteking na operatie te voorkomen) onderzoekt het effect van ademspiertraining op de incidentie van postoperatieve longontsteking en respiratoire functie na operatie bij patiënten met slokdarmkanker. Een procesevaluatie werd uitgevoerd om te evalueren wat de ervaringen zijn van patiënten die hebben deelgenomen aan de PREPARE studie en betrokken fysiotherapeuten. Het doel van de evaluatie was onderzoeken of het protocol werd uitgevoerd zoals beoogd was en eventuele knelpunten aan het licht te brengen die invloed zouden kunnen hebben op de uitkomst van de studie.
Methode: Het design was algemeen kwalitatief onderzoek. Zes semigestructureerde interviews zijn afgenomen bij patiënten die hebben deelgenomen aan de PREPARE studie en vier semigestructureerde interviews zijn afgenomen bij fysiotherapeuten die betrokken zijn bij de studie.
Resultaten: Over het algemeen waren patiënten en fysiotherapeuten positief over de PREPARE studie, vooral over de informatie en organisatie. Desondanks bleek dat contaminatie bias voorkwam (n=1), metingen na de operatie niet gedaan waren (n=1) en er problemen waren met de bediening van het ademspiertraining apparaat (n=1). De fysiotherapeuten hadden problemen met het uitvoeren van de duurmetingen en vonden de tijdsinvestering hoog.
Conclusie: De patiënten en fysiotherapeuten waren over het algemeen positief over de PREPARE studie. Het protocol werd voor het grootste gedeelte uitgevoerd zoals beoogd, wel werden er enkele knelpunten gevonden.
Klinische relevantie: Dit is de eerste procesevaluatie die is uitgevoerd bij een studie waar het effect van ademspiertraining wordt onderzocht. Deze procesevaluatie geeft meer inzicht in de uitvoering van de PREPARE studie, met de uitkomst van de PREPARE studie zouden eventuele knelpunten aangepakt kunnen worden.

ABSTRACT

Aim: Esophageal cancer is a common disease with increasing incidence. The most common treatment for esophageal cancer is surgical resection. The mortality rate of pneumonia after surgical resection is approximately 20%, compared to 3% in patients without pneumonia. The PREPARE trial (preoperative inspiratory muscle training to prevent postoperative pneumonia in patients undergoing esophageal resection) was designed to investigate the effect of inspiratory muscle training (IMT) on the incidence of postoperative pneumonia and respiratory function after esophageal surgery. A process evaluation was performed alongside this trial to investigate the experiences of patients and the involved physiotherapists participating in the PREPARE trial. The aim of this study was to evaluate the protocol of the PREPARE trial, its execution any bottlenecks that may influence the outcomes of the trial.
Methods: A generic qualitative approach was used. Six semi-structured interviews were conducted with patients who participated the PREPARE trial and four semi-structured interviews were performed with involved physiotherapists.
Results: Overall, the experiences of the patients and physiotherapists were positive, particularly on the organization and information of the PREPARE trial. However, contamination bias occurred (n=1), no measurements were performed after surgery (n=1) and there were problems with using the device (n=1). The Physiotherapists had problems with performing the endurance measurement and found the time investment high.
Conclusion: The PREPARE trial was positively evaluated by patients and physiotherapists. The PREPARE trial was performed according to protocol on most aspects, a few deviations were reported.
Clinical Relevance: This is the first process evaluation of a trial which investigate the effect of IMT. This process evaluation gives more insight in the execution of the PREPARE trial. In combination with outcome of the trial, this study may lead to an improvement of the study protocol when bottlenecks will be tackled.

Keywords: Process evaluation, inspiratory muscle training, contamination bias, protocol adherence

INTRODUCTION

Esophageal cancer is a common disease with an increasing incidence.(1) Currently, 326,600 cases are identified each year worldwide.(1) The most common treatment for esophageal cancer is surgical resection.(2) However, surgical resection has a 30% incidence of postoperative pneumonia.(2) The mortality rate of pneumonia after surgical resection is approximately 20%, compared with 3% in patients without pneumonia.(2) Therefore, it is important to decrease the incidence of pneumonia after surgical resection.

Inspiratory muscle training (IMT) is a training using an inspiratory loading device that increases inspiratory muscle strength and endurance.(3) Stronger inspiratory muscles may result in a better ventilator capacity and may delay fatigue.(3) Earlier research has shown that IMT in the preoperative phase decreases the incidence of postoperative pulmonary complications (PPCs) in patients undergoing cardiac surgery.(4) The PREPARE trial (preoperative inspiratory muscle training to prevent postoperative pneumonia in patients undergoing esophageal resection) is designed to investigate the effect of IMT on the incidence of postoperative pneumonia and respiratory function after esophageal surgery.(5)

Insight and understanding of the processes of studies investigating the effects of IMT have not been reported. It is important to know which unforeseen circumstances and bottlenecks could have influenced the outcome of the study.(6) Protocol deviations and contamination bias are examples of unforeseen circumstances that can influence the effectiveness of an intervention.(7)

Furthermore, studies differ in describing whether there was compliance. Compliance indicates the percentage of the planned training sessions that are actually performed. In the study of Hulzebos et al. no participants dropped out and no adverse events were reported.(8) However, compliance was not described, which makes it unclear if the effectiveness of the intervention was harmed by problems in performing the training. In contrast, compliance was described in the study of Van Adrichem et al.(9) They performed a RCT pilot study, whereby two preoperative IMT programs to prevent pulmonary complications in patients undergoing esophagectomy were compared. They described the average compliance of both groups (IMT-high intensity group 98.0% and IMT-endurance group 99.4%).(9) Without describing compliance it is unclear if the study outcomes are representative of the research population or that the study outcomes are influenced by not fully completing all training sessions.(10)

Contamination bias can also influence the study results. Contamination bias occurs when a patient in the control group becomes interested in the intervention and starts following it on his own or vice-versa.(7) This type of bias can lead to a reduction of the intervention effect found.(7)

Process evaluations are important to gain more insight in what happened during the

execution of the study, and makes it possible to sharpen the effective elements of the study and to tone down or eliminate the impending elements.(6) In combination with the data of the trial, it may show why the intervention could be effective in some settings but not in others.(10) This could lead to an improvement of the study protocol.

A process evaluation can be used to check whether the planned activities have indeed been executed in a uniform way and whether the target population has actually been exposed to these activities as planned. The experiences of the participants about the activities can be used to investigate why the target population has actually performed, or not performed, the activities as planned.(10) Furthermore, the experiences might explain why some participants have problems with the activities of the trial, while others did not.(10) Health care providers also play an important role in executing the trial as planned, and can influence the effectiveness of the trial.(11) When they do not fully understand the intervention of the trial, it is difficult to inform the patients about what they need to do during their participation of the trial. The opinion of the therapist about the trial can influence the behaviour of the patient during participation.(12)

The aim of this study is to investigate if the protocol of the PREPARE trial and the intervention were performed as intended and if there are any bottlenecks that influences the outcome of the trial. Therefore, a process evaluation of the PREPARE trial will be performed by investigating the experiences of patients and the involved physiotherapists participating in the PREPARE study using a qualitative approach.

METHODS

A generic qualitative research approach using semi-structured interviews was proposed for the process evaluation of the PREPARE trial.(13) A qualitative approach gives the participants the opportunity to describe their experiences of the trial in their own words.(13) The Medical Research Ethics Committee of University Medical Centre Utrecht (NL 43194.041.13) gave approval for this study.

The PREPARE trial

A summary of the PREPARE trial will be given, for the whole protocol of the PREPARE trial the research protocol could be read.(5) The PREPARE trial is an international multicentre randomised controlled clinical trial, coordinated by the University Medical Centre Utrecht (Department of Rehabilitation, Nursing Science and Sports). Patients will be recruited from six hospitals in the Netherlands, one in Ireland and one in Belgium. Recruitment started in September 2013, last recruitment is expected in December 2014.The control group receives usual care without IMT according to the local protocol. The intervention group receives an IMT program on top of usual care. The instruction of IMT is given by a physiotherapist. The POWERbreathe K-series, an electronic inspiratory muscle training and monitoring system, is used for the training. Patients have to complete 30 dynamic inspiratory efforts twice daily against 60% of the measured maximal inspiratory pressure (Pi_{max}) for two weeks. Patients are instructed through a video and the physiotherapist will contact the patient after 3 days by telephone, to ask if they need any help.(5)

Population

For this process evaluation, patients and physiotherapists, who participated in the PREPARE study, were recruited from 3 Dutch hospitals.

The study population of the PREPARE study consists of patients diagnosed with esophageal cancer and scheduled for esophageal resection with gastric conduit reconstruction by either a transhiatal esophageal resection (THE), a transthoracic esophageal resection (TTE), or minimally invasive (sometimes robot-assisted) thoraco-laparoscopic esophageal resection.(5)

The coordinating researcher of the PREPARE trial (KV) approached all potential participants for this process evaluation. The participants received an information letter. After a week, they were asked if they wanted to take part in the interview and when they agreed, an appointment for the interview was made. The interview could be performed at home (also by telephone) or at the hospital. All interviews were done by one researcher (EH).

The intent was to get a reflection of the total population, to get maximum variation; patients of different hospitals, different genders, and intervention or control group. Maximum variation increases the probability that the findings will reflect different perspectives.(14) The patient interviews took place when participation in the PREPARE trial was completed.

The inclusion criteria were:

- Finished participation of the PREPARE trial.

- Willing to sign the informed consent form.

The exclusion criteria of the PREPARE study were:
- Unable to speak after the surgery.

The in- and exclusion criteria of the PREPARE trial are listed in the study protocol of PREPARE.(5)

Data-collection

Data was collected through semi-structured interviews, based on a topic list (APPENDIX I). This topic list includes all steps of the process of the PREPARE study. The topic list for the interviews with the physiotherapist was based on the topic list that was used for the patients' interviews and adjusted based on the results of the patients interviews (APPENDIX II).
The number of included patients was based on saturation.(13) Saturation occurs when the categories are saturated and nothing new can be learned from analyzing more data. Saturation depends on variation and complexity of the topic and on the available time and resources.(13)

Data analysis

The interviews were audio taped and fully written out in a transcript. After reading the whole transcript, data was managed using Nvivo10 (QSR International Pty Ltd. Version 10, 2012). The data analysis consisted of three phases: open coding (segmenting), axial coding (describing categories) and selective coding (reassembling). In the first phase the data was broken down, examined, compared, conceptualised and categorized, this process is called open coding and this resulted in a list of codes.(15) When no new codes could be added, the open coding process was ended.(14) The next step was axial coding, which means coding around several single categories or axes.(14) This resulted in a list of categories. The third step was selective coding. In this step connections were made between the categories.(14)
A second researcher (SV) also coded and analysed the first two interviews to enhance the external validity.(13)
The data of this process evaluation was analysed before the outcome data of the PREPARE study to avoid bias in interpretation.(16)

RESULTS

Of the 10 patients that were invited to participate, 6 patients were interviewed. Reasons for not participation in the interview were:

- No interest (n=2)
- No time (n=1)
- Willing to participate, however not able to get in touch with the patient (n=1)

The demographic and background characteristics of the patients are presented in Table 1. The participants were recruited from two different hospitals. Patients were interviewed at the hospital (n=3), at home (n=1) and by telephone (n=2).

Table 1: Demographic and background characteristics of the patients

Respondent	Male/female	Age	Location Interview	Group	Hospital	Time interview (weeks after surgery)
1	female	71	hospital	control	1	9
2	male	66	hospital	intervention	1	4
3	male	71	telephone	intervention	2	5
4	female	78	home	intervention	1	8
5	female	53	hospital	control	1	3
6	male	66	telephone	control	1	7

After 6 interview with patients no new information was given. The overall experiences of the patients are shown in table 2.

The information that the 4 physiotherapists gave was additional to and in conformity with the answers of the patients. The time investment of the trial was considered higher than expected and the endurance measurement was difficult to perform. They agreed with the patients that the trial is well organized and that the information was clear.

Table 2: Overall experiences of the patients.

Respondent	Doubts about participation	Organisation	Patient information letter	Randomisation	Adherence	Opinion about supervision	Would participate again
1	No	Good	Usual care was unclear	Disagree	No	Good	Yes
2	Yes	Good	Clear, but a lot	Clear	Yes	Good	Yes
3	No	Good	Clear, but a lot	Clear	Yes	Bad	Yes
4	Yes	Good	Instructions of IMT device were unclear	Unclear	Yes	Good	Yes
5	No	Good	Clear, scanted the text	Clear	Yes	Good	Yes
6	No	Good	Clear	Clear	Yes	Good	Yes

Overall experiences

Patients

All patients (n=6) were positive about participating in the PREPARE trial. The information was clear (n=4), the organisation was good (n=5) and they knew what they were supposed to do during participation (n=5). None of the patient in the intervention group (n=3) watched the instruction video, and only the partner of respondent 2 did so and reported the video as clear. Especially the fact that the appointments at the hospital where scheduled at days when they already had an appointment was experienced as positive (n=6). If this was not possible, the patients received travelling expenses for an extra appointment at the hospital only for PREPARE (n=2).

Physiotherapists

All physiotherapists (n=4) were satisfied as well with the organisation of the PREPARE trial. The information they received was clear, and so was the information for the patients. They received no negative reactions of the patients about the information.

Randomisation and blinding

Patients

In 4 cases the randomization went without problems. In 2 cases the randomization was not totally clear. Reasons were:

- One patient did not know to which group he or she was allocated.

- One patient in the control group thought that the IMT device belonged to usual care, so this patient collected an IMT threshold device by him or herself and followed the intervention by him or herself.

All patients answered that the randomization was kept secret for the physiotherapist who performed the measurements.

Physiotherapists

There were no problems with the randomization. All physiotherapists said that the randomization was kept secret as prescribed in the protocol.

Adherence

Patients

Of all patients, 2 patients did not completed the protocol of the PREPARE trial as was described.

- Started an IMT with a threshold device, while participating the trial in the control group (n=1)
- There were problems with the IMT device (n=1)

Not all the measurements were done after surgery (n=2), the patient could not remember if the measurements after surgery were performed (n=1) or no measurements were done at all after surgery (n=1).

The IMT protocol was easy to follow (n=3). Patients told that they trained twice a day like was asked. One patient did not know how to change the resistance and called the physiotherapist about this. During an appointment in the hospital, the patient was properly instructed in changing the resistance in the IMT device and trained according to protocol.

No patient of the intervention group trained more or less then was asked. Reasons were that they had the idea that it was positive for the lung function (n=1), because the protocol says so (n=1) and nice to see that you improve yourself (n=1).

In general it was no problem to do the measurements before and after the intervention period if it was possible with their condition at that time (n=5). An extra visit by a physiotherapist was not perceived by the patients as an additional burden, because they were already visited by so many different hospital staff. It was no problem for them that the physiotherapist performed the measurements during hospitalization (n=4). Some of the patients did not feel like doing the measurements (n=1) but this did not influence when the measurements eventually were done.

Physiotherapists

The physiotherapists agreed that when a patient was in bad health after surgery, the measurements would be postponed to a later time. Especially the inspiratory muscle

endurance measurement was difficult to perform by the patients after surgery. This measurement was skipped from the protocol, which meant that the physiotherapists did not have to burden the patients more than necessary and it also decreased the time investment of the physiotherapists.
When patients are familiar with the device, they are perfectly able to follow the IMT intervention (n=2). It would be better if the device is easier to use to decrease the time investment at the beginning of the study by the intervention group. The opinion of the physiotherapist about the problem with the device of one patient was that the problem was solved well. The only thing that could go better was to increase the time between the start of the problem and the appointment in the hospital to solve the problem. There were no other problems that could not be solved by telephone. They did not have other examples of patients that did not follow the intervention protocol.

Supervision of the intervention

Patients

Almost all patients of the IMT group were positive about the supervision (n=2). The phone calls were considered positive and they did not want to have more contact than once a week (n=2).
One patient was not satisfied with the supervision. They did not call him or her during the intervention. The probable reason the patient gave was that there was a short time of IMT before surgery (2 weeks). He or she would have been able to contact the physiotherapist about the matter but at the same time he or she did not think it was his or her responsibility to contact the physiotherapist about it.

Physiotherapist

The physiotherapist (n=1) was satisfied with the contact with the patients. Contact by phone was no problem at all, in fact it would only take more time to visit the patient.

Suggestion of improvement

Patients

There were no suggestions of improvement for the protocol of the PREPARE trial. It was no problem for patients to follow the descriptions in the PREPARE protocol, exceptly when they were too sick to participate (n=6). Taking into account the experiences they have with participating in the PREPARE trial; all patients would participate in the trial again.

Physiotherapists

All physiotherapists would cooperate again with the PREPARE study if they would be asked (n=3). Suggestions of improvement were:

- Skipping the inspiratory muscle endurance measurement is a good improvement because of the time investment and the amount of effort it costs the patient (n=3).
- An easier device would help to decrease the time investment of the intervention group at the beginning of the study (n=1).

DISCUSSION

The experiences of patients and involved physiotherapists about participating in the PREPARE trial were studied. Overall, the experiences of the patients and physiotherapists were positive, particularly on the organization and information of the PREPARE trial. However, contamination bias occurred (n=1), no measurements were performed after surgery (n=1) and there were problems with using the device (n=1). The physiotherapists faced problems with performing the endurance measurement and found the time investment high.

Evaluation of contamination bias in RCTs is recommended, because this bias can lead to a reduction of the intervention effect. Moulart et al. performed an evaluation of the 'Activity and Life After Survival of a Cardiac Arrest' (ALASCA) study. (17) They described that 6 persons refused the intervention while they continued their participation in the study. Contamination bias thus seems to occur. In our study contamination bias occurred the other way around: one patient in the control group retrieved an IMT threshold device on its own initiative and started training. This may have resulted in contamination bias. To decrease contamination bias, it is important that usual care is clear for the patient. When the patient thinks that the intervention is a part of the usual care, the risk that the intervention will be followed by the patient in the control group is higher than when it is clear what usual care entails. More research is necessary to investigate if contamination bias occurred in the other centers. It is possible that incorrect information before participation harmed the effectiveness of the trial.(18)

In this process evaluation, protocol adherence was investigated from patients' and physiotherapists' point of view. It was investigated whether there was adherence and if not, what reasons were for non-compliance. Protocol adherence was reported when the protocol was not executed as planned; irrespective of this was of influences of the patients, therapist of an external factor. Dettling et al. examined the initial effectiveness of pre-operative IMT on the incidence of pneumonia and the length of hospital stay in patients scheduled for an oesophagectomy. (19) They performed endurance measurements on the first days after surgery. Of the 87 patients, 9,2% performed the endurance measurement on the first day after surgery to 34.5% on the tenth day. Reasons they give for the missing values were

tiredness, oxygen suppletion, nasogastric tubes and post-operative complications. Missing values can be cause to little power to give a conclusion.(20) In our study, all patients said to have followed the protocol of the PREPARE trial as was asked. Thus, protocol adherence seems to be no issue in the PREPARE trial. However, there were some issues with protocol adherence in the measurements. In some instances, the measurements were not completed after surgery because of the patients' illness or because the physiotherapist did not do any measurements at all (n=1). The reason for this is not known. Time investment could be a reason for not performing the measurements after surgery, because the physiotherapists found that the time investment was higher than they expected. However, the endurance measurement was skipped from the protocol because it was not feasible. More research is necessary to affirm that protocol adherence by patients participating in the PREPARE trial is not an issue. Especially patients from other hospitals need to be interviewed, to investigate if there are differences between protocol adherence in the hospitals. This concerns also the protocol adherence of the physiotherapists. When it is clear whether there are issues with protocol adherence and in which part of the protocol they occur, the facilitators and barriers can be explored to improve the protocol.(11)

One of the reasons to perform a process evaluation is to investigate if and why compliance occurred.(10) It is important that the training protocol suits the research population so that they can perform all training sessions.(10) In RCTs using IMT as intervention there are differences in describing the compliance. Some studies do not describe compliance at all. (8,21) Some studies do describe the compliance: Fry et al. describe a compliance of 81% in the intervention group (22) and Van Adrichem et al. describe a compliance around 100% in their study results.(9) Because of the high compliance in the studies of Fry et al. and Van Adrichem et al., the results seem to be a good reflection of the effect of the protocol. In this study one patient did have problems with using the device, but this issue was resolved after one week. It is positive that the problem was resolved and the communication between patient and physiotherapist went well. However, this patient missed one week of training. The other 2 patients of the intervention group said that they performed 30 breathings twice a day like was asked. Therefore, compliance seems to be sufficient, however the real percentage of compliance should be evident from the results of the PREPARE trial.

Strength of this process evaluation is that it is performed by an independent researcher, who does not have any benefit from the outcomes of this study. Furthermore, this study is a first process evaluation of an RCT using IMT. To compare the results of this study, other process evaluations are needed.

A limitation of this research is the limited number of interviews. However, after four

patients no new information was given about the PREPARE protocol. Two more interviews were done to confirm the saturation and no new information was added. Other process evaluations show saturation after more interviews.(23-25) Reasons could be because they tackle a different topic, higher variation in the target population or performance of the process evaluation after finishing the evaluated trial.(14)

Another limitation is that for this research, only patients who completed the trial were interviewed. Patients who dropped out of the trial are possibly more critical about the trial. Moreover, almost all patients were treated in the same hospital. When there is more variation of subjects, it is more likely that there would be more difference in the answers. This could give a more complete evaluation of the trial.

It can be stated that interviewing by telephone and face to face has no influence on the received data for this research: there are no remarkable differences in the types of answers the patients gave and the duration of the interviews were almost equal.

CONCLUSION

To conclude, the PREPARE trial was positively evaluated by patients and physiotherapists. The protocol of the PREPARE trial was performed according to the protocol on most aspects, a few deviations were reported.
Recommendations for further research are to expand this process evaluation with patients who have not completed the PREPARE trial and patients from other centres to get a more complete representation of the execution of the PREPARE trial. Moreover, other process evaluations are needed to compare the results of this study with other IMT studies that differ in setting.

CONFLICT OF INTEREST STATEMENT

None.

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APPENDIX I

Topic lijst Patiënt

Voorstellen	Ik volg de master Fysiotherapiewetenschap aan de Universiteit van Utrecht. Voor mijn afstudeeronderzoek doe ik een evaluatie van de PREPARE studie. Mijn begeleider is Karin Valkenet, de coördinator van de PREPARE studie.
Doel onderzoek	Het doel van het onderzoek is om het studieprotocol van PREPARE te evalueren om eventueel verbeterpunten aan te dragen.
U / jij	Wilt u met u of je worden aangesproken?
Interview	Dit interview zal een half uur gaan duren. Als een vraag niet helder is, kunt u dit aan geven en zal ik de vraag anders stellen. U kunt geen foutieve antwoorden geven.
Anoniem	U mag alles vertellen wat u kwijt wilt. De informatie zal anoniem worden verwerkt.
Opnemen	Vindt u het goed als dit interview wordt opgenomen?
Contact gegevens	De contact gegevens staan op de informatiebrief. Deze kunt u gebruiken als u achteraf nog vragen of op-/aanmerkingen heeft of iets vergeten bent te vertellen.
Vragen	Hebt u vooraf vragen?

Benadering	Wat vond u ervan dat u werd benaderd voor de PREPARE studie? Polikliniek door chirurg/verpleegkundige (wat was zijn/haar rol?) timing - Wat was uw mening over deze benadering? <u>Telefoongesprek Karin</u> - Wat was uw mening over deze benadering? <u>Afspraak voor de metingen en loting</u> Wat waren uw verwachtingen ten aanzien van de studie toen u besloot deel te nemen? Waarom besloot u deel te nemen aan het onderzoek?

Informatie	Wat vond u van de informatie die u kreeg voorafgaande aan de deelname? - Duidelijkheid - Volledigheid - Te veel/weinig Indien iets niet duidelijk was: Hebt u daarover contact opgenomen met de therapeut?
Nulmeting	Wat vond u van de metingen die werden gedaan, de aller eerste keer? Zwaar, lastig, vervelend
Interventie/controle groep	Wat vond u ervan dat u in de interventie/controle groep zat?
Volgen protocol	Waren de instructies helder? Hoe was het voor u om de instructies te volgen? Hebt u zich eraan gehouden?
Drempels	Bij IMT: Hebt u alle dagen het trainingsprotocol kunnen volgen? Wat waren de redenen hiervoor? → doorvragen Hoe hebt u de training ervaren? Instructievideo bekeken? Trainingsdagboek duidelijk? Apparaatje makkelijk/ingewikkeld? Bij controle: Hebt u een manier gezocht om toch de ademspieren te trainen? Waarom wel/niet?
Begeleiding	Welke begeleiding van de fysiotherapeut is er geweest voor de operatie? Hoe hebt u dit ervaren? Wat hebt u als prettig ervaren/wat heeft u als minder prettig ervaren? Wat zijn uw suggesties om de begeleiding beter te maken?
Vervolgmetingen	Wat vond u van de vervolg metingen die werden gedaan? Zwaar, lastig, vervelend Voor vs Na de operatie
Afsluiting studie	Is er na afloop van de studie nog contact geweest? Hoe hebt u dit ervaren?

Ervaring	Zou u met de ervaring van nu weer beslissen om deel te nemen aan het onderzoek? Waarom wel/niet? Zou u dingen anders doen? Hetzelfde doen? - Zou u zich meer/minder inspannen om het programma te volgen?

Wilt u verder nog iets vertellen over de studie?

Mocht u later iets te binnenschieten, laat het me dan gerust weten. U kunt mij bereiken via Karin Valkenet, haar contact gegevens staan op de informatiebrief.

Mag ik u hartelijk danken voor uw deelname aan het interview en uw openheid.

APPENDIX II

Topic lijst Fysiotherapeut

Voorstellen	Ik volg de master Fysiotherapiewetenschap aan de Universiteit van Utrecht. Voor mijn afstudeeronderzoek doe ik een evaluatie van de PREPARE studie. Mijn begeleider is Karin Valkenet, de coördinator van de PREPARE studie.
Doel onderzoek	Het doel van het onderzoek is om het studieprotocol van PREPARE te evalueren om eventueel verbeterpunten aan te dragen.
U / jij	Wilt u met u of je worden aangesproken?
Interview	Dit interview zal een half uur gaan duren. Als een vraag niet helder is, kunt u dit aan geven en zal ik de vraag anders stellen. U kunt geen foutieve antwoorden geven.
Anoniem	U mag alles vertellen wat u kwijt wilt. De informatie zal anoniem worden verwerkt.
Opnemen	Vindt u het goed als dit interview wordt opgenomen?
Contact gegevens	Wanneer u achteraf nog vragen of op-/aanmerkingen heeft of iets vergeten bent te vertellen, kunt u mij bereiken via Karin Valkenet.
Vragen	Hebt u vooraf vragen?

Benadering	Wat vindt u ervan om deel uit te maken van de PREPARE studie? Hebt u vaker geholpen bij een onderzoek? Wat is er aan dit onderzoek anders dan bij andere onderzoeken?
Informatie	Wat vond u van de informatie die u kreeg voorafgaande aan het onderzoek? - Duidelijkheid - Volledigheid - Te veel/weinig Indien iets niet duidelijk was: Hebt u daarover contact opgenomen met de coördinator? > hoe verliep het contact? Wat vond u van de informatie die de patiënt kreeg voorafgaande aan de deelname?

Nulmeting	Wat vond u van de metingen die werden gedaan? Voor operatie. Na operatie. Was het haalbaar? Hoe reageerde de patiënt op het afnemen van de metingen? Ging het volgens de planning?
Interventie/controle groep	Wat was uw rol bij de loting? Wist u van de patiënten in welke groep ze zaten? Wat is uw mening over IMT?
Volgen meetprotocol	Waren de instructies in meetprotocol helder? En voor de patiënt? Hoe was het voor de patiënt om de instructies te volgen? Hebt u alle metingen gedaan? Wat ging er goed, wat ging er mis?
Drempels	Bij IMT: Volgen de patiënten alle dagen het trainingsprotocol? Wat waren de redenen hiervoor? → doorvragen Hoe heeft u de training ervaren? En de patiënten? Instructievideo bekeken? Trainingsdagboek duidelijk? Apparaatje makkelijk/ingewikkeld? Hoe vond je het om elke week te bellen? Lukt dat? Heb je de gevraagde trainingsparameters op de trainingskaart genoteerd tijdens de evaluaties? Waarom wel/niet? Bij controle: Hebben de patiënten manieren gezocht om toch de ademspieren te trainen? Waarom wel/niet? Hoe was de tijdsinvestering? Haalbaar?
Begeleiding	Welke begeleiding in het kader van PREPARE van de fysiotherapeut is er geweest voor de operatie? Hoe hebt u dit ervaren? Wat hebt u als prettig ervaren/wat heeft u als minder prettig ervaren? Wat zijn uw suggesties om de begeleiding beter te maken? Telefonische begeleiding, prettig/onprettig?

Afsluiting studie	Is er na afloop van de studie nog contact geweest mbt PREPARE met de patiënten? Hoe hebt u dit ervaren? Hoe heeft de patiënt dit volgens u ervaren?
Ervaring	Zou u met de ervaring van nu weer beslissen om deel uit te maken van het onderzoek? Waarom wel/niet? Zou u dingen anders doen? Hetzelfde doen?

Wilt u verder nog iets vertellen over de studie?

Mocht u later iets te binnenschieten, laat het me dan gerust weten. U kunt mij bereiken via Karin Valkenet.

Mag ik u hartelijk danken voor uw deelname aan het interview en uw openheid.