UNIVERSITY OF COPENHAGEN
FACULTY OF HEALTH AND MEDICAL SCIENCES

High Intensity Functional Training in the Rehabilitation of Cancer Survivors

Study protocol of a pragmatic clinical trial

Andreas Lund Hessner, PT, MSc

Henning Langberg, Professor

Jette Vibe-Petersen, MD

Karen Trier, PT, Msc

Maja S. Sommer, PT, PhD

Rikke Daugaard, PT, Msc

Rasmus Tolstrup Larsen, PT, MSc

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Title page

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Corresponding and first author: Andreas L. Hessner[1], PT, MSc. (hessnerfysioterapi@gmail.com)
Henning Langberg[1]
Jette Vibe-Petersen[2]
Karen Trier[2]
Maja S. Sommer[2]
Rikke Daugaard[2]
Rasmus T. Larsen[1], PT, MSc. (rala@sund.ku.dk)

Affiliation
[1]CopenRehab, Section of Social Medicine, Dept. of Public Health,
University of Copenhagen, Henrik Pontoppidansvej 6, 1., 2200 Copenhagen N.
[2]Centre for Cancer and Health Copenhagen, Nørre Allé 45, 2200 Copenhagen N.

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Background and rationale

Cancer survivors experience a variety of ongoing physical and psychological symptoms associated with both disease and treatment (1,2). Additionally, cancer survivors have an increased risk of serious chronic health sequelae and comorbid conditions such as cardiovascular disease and diabetes (2). These poor health outcomes among cancer survivors have led to greater emphasis on interventions to enhance health outcomes such as health-related quality of life (HRQoL) and cancer-related fatigue (CRF) (3).

Aerobic training as well as resistance training are both exercise interventions associated with a number of health benefits in survivors of a variety of cancers (4–7). Thus, clinical guidelines worldwide recommend both regular aerobic- and resistance training as an essential part of the

rehabilitation of cancer survivors during and after active cancer treatment (1,8,9).
Furthermore, aerobic training and resistance training performed at high intensity has been reported as a feasible and safe intervention for patients with various different cancer diagnosis and in different stages of cancer. It can provide objective physiological benefits as well as improve HRQoL, CRF and depression among cancer survivors (4,5,7,10–12).
High Intensity Functional Training (HIFT) has been defined as a style of training that incorporates functional, multimodal movements, performed at relatively high intensity, and designed to improve parameters of general physical fitness and performance (13). In recent years HIFT has gained increasing attention in the fitness industry and in research (14), especially due to the increased popularity of the HIFT program CrossFit© (13). Recently trials, using HIFT protocols, have reported benefits in healthy adults including physiological improvements such as increased oxygen consumption, improved body composition and bone health (15,16).
One identified study by Heinrich et al examined the effectiveness and feasibility of 5 weeks of HIFT among cancer survivors with a variety of cancer diagnoses. The study included 8 participants and reported that the intervention was well-received, feasible and associated with a significant improvement in emotional functioning and body composition.

HIFT is viewed as a promising type of training (13,17), that has shown numerous physiological benefits (15,16,18) and has shown preliminary effectiveness and feasibility among cancer survivors (17).
Furthermore, several reports and clinical guidelines recommend the prescription of exercise programs that are enjoyable and facilitates social interactions, motivation and continued participation to reduce risk of the development of comorbid conditions and late-appearing effects of cancer and its treatment (1,8,19). HIFT has been reported to be associated with higher levels of enjoyment than more traditional resistance training, and to facilitate adherence, continued participation and sense of community among healthy participants (18,20).

Objective

The primary objective of this pragmatic clinical trial is to test the feasibility of the intervention in a real world setting and secondary, to describe whether the HRQoL of the participants changes from baseline to end-point and follow up time points. Furthermore, we will investigate the association between the leisure-time HIFT and the HRQoL.

Methods: Participants interventions and outcomes

This study protocol is reported according to the Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols (SPIRIT-PRO) Extension.

Design and study setting

This study is a single group clinical trial. A pragmatic design will be applied for this study to increase transferability, generalizability and the external validity of the results into clinical practise. Thus, the clinical setting for the intervention will be at the municipality rehabilitation centre, *Centre for Cancer and Health Copenhagen* (CCHC), in the capitol region of Denmark.
The exercise intervention will be implemented as a part of regular practice at the centre and will be supervised by CCHC's physiotherapists. Two co-authors of this protocol (MS and RD) are employed as physiotherapists at CCHC. They have contributed in designing this study to fit the clinical reality and the specific patient group at CCHC. This is another way increasing the external validity of the results of this study, and to 'bridge the gap' between research and clinical practise. This implementation of community-based clinicians in physiotherapy research has previously been recommended in the literature (21,22).

Eligibility criteria

Due to the pragmatic design of this study, only few inclusion- and exclusion criteria will be applied. Patients will be considered eligible for inclusion when they; 1) are at least 18 years old, 2) are referred to the centre for cancer rehabilitation from any hospital or private practising general practitioner in the Capital Region in Denmark, 3) Choosing to participate in group based high intensity functional training that is offered at CCHC as part of their physical rehabilitation. Eligibility for participation in this study will be regardless of cancer treatment and the stage of the cancer. Thus, both patients undergoing active cancer treatment, patient who have completed active treatment as well as chronic cancer survivors will be considered eligible for participation in this study.
The following exclusion criteria will be applied for this study: 1) Not able to reply to the questionnaire due to mental impairment, 2) Patients who are not able to read and understand

Danish, 3) Patients who does not have an e-mail address because of the application of online-based questionnaires.

Intervention

The exercise intervention for this study will be HIFT, as defined by Feito et al and described in the introduction of this study protocol (13). The program design and template will be based on the principles of the HIFT program called CrossFit®. CrossFit is described as a strength and conditioning program that focuses on "constantly varying functional movements, performed at a relatively high intensity" (23). CrossFit training includes a variety of elements from gymnastics (e.g., floor, bar and ring exercises), weightlifting exercises (e.g., squats, cleans, snatches and presses with a barbell, dumbbell or kettlebell), and cardiovascular activities (e.g., running or rowing) (24).

All group training sessions will take place in a clinical setting at CCHC.
The full exercise protocol template is designed as a 38-week HIFT program, as the inclusion of participants will be consecutive. All participants will complete 16 weeks of twice weekly group-based HIFT sessions, under the supervision of two physiotherapists, specifically trained to deliver the HIFT program. Given the consecutive nature of this inclusion process, the participants will initiate the group-based training at different dates between august 5th 2019 and January 5th 2019 (see figure 2 for process of HIFT program implementation and figure 3 for timeline of the study period with important dates).

Each training session will last for one hour and 15 minutes and will include a general warmup, a strength-focused section including 1-3 exercises and a aerobic-focused workout.
The exercise program is not developed to include a general progression in terms of resistance, intensity or volume over the cause of 38 weeks. An exercise compendium will be developed to meet one of the key principles of CrossFit, that is scalability (25). The compendium will include movement standards as well as progressions and regressions of all included exercises. This is to assist the supervising physiotherapists in choosing the relevant level of intensity and exercise difficulty for each participant, and to allow for individual progression over the cause of the 16-week exercise intervention period for each participant.

Patient-reported outcomes

EORTC:

EORTC QLQ-C-30 includes five functional domains (physical, role, cognitive, emotional and social, where higher scores represent greater function or quality of life) and three symptom scales (fatigue, pain and nausea). Functional and symptom scales range from 0 to 100. Higher values on functional scales equal a higher level of functioning. Higher values on symptom scales equal higher symptom burden. EORTC QLQ-C-30 is chosen for it's established reliability and validity with specific emphasis on use in cancer populations (26, 27).

GLTEQ:

Leisure time physical activity (LTPA) will be assessed using an original Danish translation of the Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ) .The GSLTPAQ is frequently used in oncology research to assess LTPA.

The GSLTPAQ is a 4-item self-administered questionnaire. The first three questions ask for information on the number of times the respondant engages in mild, moderate and strenuous LTPA bouts of at least 15 min duration in a typical week. A score is then calculated for total leisure time based on the numerical values attributed to each of the three categories (9 for strenuous, 5 for moderate and 3 for light) multiplied by the frequency of the activity. The scores derived from this method is called a Leisure Score Index (LSI). In addition, scores obtained from moderate and strenuous physical activity can be used to classify respondents into active and insufficiently active categories.
A recently published systematic review by Amireault et al, supports the use of the GSLTPAQ in oncology research and the interpretation of the LSI for assessing relative change in PA among cancer survivors.

Primary outcomes

HRQoL will be evaluated using the Global Health Status/Quality of Life item from the EORTC QLQ-C-30 questionnaire. The item ranges from 0 to 100, and higher values equal higher HRQoL.

Time frame: for each participant at baseline + end point at 16 weeks + follow up at 3 month and 12 months)

Secondary outcomes

The secondary outcomes include functional scales (physical, role, emotional, cognitive, and social) and symptom scales (fatigue, nausea and vomiting, pain, dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties) from the EORTC QLQ-C30 questionnaire).

In addition to the EORTC QLQ-C30 scales, leisure-time exercise will be included as a secondary outcome and will be assessed using the GSLTPAQ, including the frequency and duration of mild, moderate and strenuous exercise.

[Time frame for each participant: Baseline + end point at 16 weeks + follow up at 3 months and 12 months]

Continued participation in any high intensity functional training (post-intervention HIFT) will be assessed using a single-item modified version of the (GSLTPAQ) asking participants: *During a typical 7-Day period (a week), how many times on the average do you do High Intensity Functional Training (I.E. CrossFit) for more than 15 minutes during your free time*. The participant responds by typing how many times per week, starting from zero.

[Time frame: for each participant at follow up at 3 month and 12 months]

Participation timeline

The inclusion of participants will be consecutive as patients are referred to CCHC for physical cancer rehabilitation from various hospitals in the Capital Region in Denmark (see figure 1 for participation flow of each participant).
Self-reported baseline data will be collected using online questionnaires sent out to patients via email within four days prior to beginning the supervised HIFT intervention. After completing the 16 weeks of high intensity functional training the patient will receive an end point questionnaire. Three months following completing the exercise intervention, participants will be contacted via email to complete a follow-up questionnaire also including questions regarding continued participation in HIFT. All participants will receive an identical follow-up questionnaire 12 month

after completing the intervention.

Sample size

Due to the exploratory nature of this study, no power calculation will be conducted. As the inclusion of participants will be consecutive, the anticipated number of included participants will be estimated based on the average monthly number of patients that begins the group based training during clinical practise at the centre. The average number of patients who is referred to the rehabilitation centre and who begins the HIFT training every month is 6 and thus, it is expected that a total of approximately 30 participants will be included in this study during a 22-week consecutive inclusion period that runs from august 5th 2019 to January 5th. All participants will be asked to complete both baseline-, end point- and three-month follow-up assessment.

Recruitment

Due to the pragmatic design there will be no recruitment though advertisement. Recruitment will take place by asking eligible patients referred to CCHC, if they would like to participate in the study. This recruitment will take place during an initial rehabilitation planning session with a physiotherapist two days prior to the first HIFT session. Patients will be made aware that they have two days to consider participating in the study (written participant information can be found in appendix 1).

Methods: Data collection, management and analysis

Data collection methods

Plan for assessment and collection of outcomes

All primary and secondary outcomes are participant-reported and will be administered through the online survey tool: SurveyXact. All included participants will receive an email with an electronic SurveyXact-invitation to the baseline questionnaire the same days as providing written consent to participate in the study. On the day of the final HIFT session (week 16), the participants will receive a similar SurveyXact-invitation with the end-point questionnaire. The three and 12-month follow up assessments will be administered in identical ways to the end-point assessment.

Patient characteristics

Demographic variables will be included in the baseline questionnaire. These will include self-reported information about: sex, body mass index, educational level, employment, smoking status and physical activity level, and will be collected together with information on cancer type, time since cancer diagnosis, time since active treatment and cancer treatment type.

Registration of adverse events, plans to promote participant retention and complete follow up:

Adverse events and reasons for drop out from discontinued participant will be collected by practising physiotherapists at CCHC.

To minimize non-response and loss to follow-up participants will receive a reminder by email 4 and 14 days after receiving the email with end-point and follow-up questionnaire if they haven't provided their responses.

Data management

All outcomes will be handled and stored electronically on a secure server for personal data, located at the University of Copenhagen.

No personal data will be exported from SurveyXact without pseudonymization. Complete anonymization of all data will be done after the last follow up period. Data protection agency approval Reference number: 514-0306/19-3000

Statistical methods

Descriptive statistics will be used to summarize patient characteristics including age, sex, cancer diagnosis and type of treatment. Furthermore, leisure-time HIFT exercise and HRQoL at baseline will be summarized using the GSLTPAQ LSI score and the EORTC QLQ-C30 GH score respectively. Quantile Quantile plots and histograms will be used to evaluate distribution of standardized residuals. Continous data with normally distributed standardized residuals will be summarized using parametric statistics. Continous data with without normally distributed standardized residuals will be summarized as ordinal data, using non-parametric statistics. Categorical data will be summarized using frequencies and % of total.

The EORTC QLQ outcomes will be conducted according to the EORTC QLQ-C30 scoring manual (ref fayes 2001). Numerical data for each outcome with normal distributed standardized residuals, will be analysed from baseline to end-point with parametric statistics (paired t-test with equal variance). Single-Factor Repeated Measures Design will be conducted with a repeated measures one-way analysis of variance with four within subject time levels: baseline, end-point, three month follow up, and 12-month follow up. Summary statistics will include mean and confidence intervals for each outcome.

Numerical data for each outcome, without normal distributed standardized residuals, or ordinal data will be analyzed from baseline to end-point with non-parametric statistics (Wilcoxon signed-ranks test). Single-Factor Repeated Measures Design will be conducted with a Friedman two-way analysis of variance by ranks with four within subject time levels: baseline, end-point, three months follow up, and 12-month follow up. Summary statistics will include medians and interquartile ranges for each outcome, and visualizations will include bar charts with confidence intervals.

The association between leisure-time HIFT exercise and HRQoL will be analyzed on each time point with a linear regression model. To test whether the associations varies, the coefficients from the linear regression analyses will be compared.

Stata 15.1 (StataCorp, College Station, TX, USA) will be used for all statistical analyses and illustrations and an alpha level of 0.05 or less will be considered statistically significant.

Ethics and dissemination

The study will be performed according to the Declaration of Helsinki.
The Regional Scientific Ethics Committee of Capitol Region in Denmark has reviewed the outline of this study. The committee waived the need for ethical approval as the intervention in the study is a part of the regular practice at the CCHC. Thus, the committee proclaimed that the study included "no or minimal health intervention". Such studies can be implemented without permission from the Ethics Committee according to Danish legislation (Committee Act § 2).
All included participants will provide written informed consent to participate in this study.
The study findings will be disseminated in peer reviewed journals and will be presented at national conferences.

Locations

Center for Kræft og Sundhed København, Capital Region, Denmark, 2200 Copenhagen N.

Collaborators

Section of Social Medicine, Dept. of Public Health, Faculty of Health. University of Copenhagen.
Gothersgade 160, 3. sal
1123 København K

Principal investigator

Andreas Lund Hessner

Authors contributions

ALH (principle investigator. ALH is the study coordinator and is responsible for, data collection, developing the exercise intervention program and drafting of the manuscript. ALH and RT are responsible for data analysis. All authors contributed to the design of the study. All authors will edit and approve the final manuscript.

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No funds are present at current stage.

Abbreviations (In chronological order)

CS – Cancer Survivors
HRQoL – Health-related Quality of Life
CRF – Cancer-Related Fatigue
HIFT - High Intensity Functional Training
CKSK – Center for Kræft og Sundhed København (Center for Cancer and Health Copenhagen)
WOD – Workout of the Day
EORTC QLQ-C30 – European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-C30
GLTEQ – Godin Leisure-time Exercise Questionnaire

Declarations of interests

ALH and RTL are both part time employees at the CrossFit affiliate CrossFit Copenhagen Aps. CrossFit Copenhagen has supplied some additional exercise equipment for the intervention and offered the five supervising physiotherapists from CCHC spots on their Trainers Course in order to develop and improve the physiotherapists HIFT-specific

instruction skills. ALH and RTL have not received any funds neither CrossFit Copenhagen or CCHC, nor will they during the conduction of this study. The study is not a part of ALH and RTL's occupation at CrossFit Copenhagen.

References

1. Schmitz KH, Courneya KS, Matthews C, Demark-Wahnefried W, Galvão DA, Pinto BM, et al. American College of Sports Medicine roundtable on exercise guidelines for cancer survivors. Med Sci Sports Exerc. 2010 Jul;42(7):1409–26.
2. Pachman DR, Barton DL, Swetz KM, Loprinzi CL. Troublesome symptoms in cancer survivors: fatigue, insomnia, neuropathy, and pain. J Clin Oncol. 2012 Oct 20;30(30):3687–96.
3. Richards M, Corner J, Maher J. The National Cancer Survivorship Initiative: new and emerging evidence on the ongoing needs of cancer survivors. British Journal of Cancer. 2011 Nov;105(S1):S1–4.
4. Cramp F, James A, Lambert J. The effects of resistance training on quality of life in cancer: a systematic literature review and meta-analysis. Support Care Cancer. 2010 Nov;18(11):1367–76.
5. Cheema B, Gaul CA, Lane K, Fiatarone Singh MA. Progressive resistance training in breast cancer: a systematic review of clinical trials. Breast Cancer Res Treat. 2008 May;109(1):9–26.
6. Spence RR, Heesch KC, Brown WJ. Exercise and cancer rehabilitation: a systematic review. Cancer Treat Rev. 2010 Apr;36(2):185–94.
7. Fuller JT, Hartland MC, Maloney LT, Davison K. Therapeutic effects of aerobic and resistance exercises for cancer survivors: a systematic review of meta-analyses of clinical trials. Br J Sports Med. 2018 Oct;52(20):1311.
8. Hayes SC, Spence RR, Galvão DA, Newton RU. Australian Association for Exercise and Sport Science position stand: optimising cancer outcomes through exercise. J Sci Med Sport. 2009 Jul;12(4):428–34.
9. Rock CL, Doyle C, Demark-Wahnefried W, Meyerhardt J, Courneya KS, Schwartz AL, et al. Nutrition and physical activity guidelines for cancer survivors. CA Cancer J Clin. 2012 Aug;62(4):243–74.
10. Salvi R, Meoli I, Cennamo A, Perrotta F, Saverio Cerqua F, Montesano R, et al. Preoperative high-intensity training in frail old patients undergoing pulmonary resection for

375 NSCLC. Open Med (Wars). 2016;11(1):443–8.
376 11. Edvardsen E, Skjønsberg OH, Holme I, Nordsletten L, Borchsenius F, Anderssen SA.
377 High-intensity training following lung cancer surgery: a randomised controlled trial. Thorax. 2015
378 Mar 1;70(3):244–50.
379 12. Stefanelli F, Meoli I, Cobuccio R, Curcio C, Amore D, Casazza D, et al. High-
380 intensity training and cardiopulmonary exercise testing in patients with chronic obstructive
381 pulmonary disease and non-small-cell lung cancer undergoing lobectomy. Eur J Cardiothorac Surg.
382 2013 Oct;44(4):e260-265.
383 13. Feito Y, Heinrich KM, Butcher SJ, Poston WSC. High-Intensity Functional Training
384 (HIFT): Definition and Research Implications for Improved Fitness. Sports (Basel). 2018 Aug
385 7;6(3).
386 14. Thompson WR. WORLDWIDE SURVEY OF FITNESS TRENDS FOR 2018: The
387 CREP Edition. ACSM's Health & Fitness Journal. 2017 Dec;21(6):10.
388 15. Feito Y, Hoffstetter W, Serafini P, Mangine G. Changes in body composition, bone
389 metabolism, strength, and skill-specific performance resulting from 16-weeks of HIFT. PLoS ONE.
390 2018;13(6):e0198324.
391 16. Heinrich KM, Spencer V, Fehl N, Poston WSC. Mission essential fitness: comparison
392 of functional circuit training to traditional Army physical training for active duty military. Mil Med.
393 2012 Oct;177(10):1125–30.
394 17. Heinrich K.M. High-intensity functional training improves functional movement and
395 body composition among cancer survivors: a pilot study. 2015 Nov;
396 18. Bechke E, Kliszczewicz B, Feito Y, Kelemen H, Nickerson B. Resting cardiac
397 autonomic activity and body composition following a 16-week high-intensity functional training
398 intervention in women: A pilot study. Journal of Human Sport & Exercise. 2017 Jul;12(3):680–8.
399 19. Ganz PA, Earle CC, Goodwin PJ. Journal of Clinical Oncology update on progress in
400 cancer survivorship care and research. J Clin Oncol. 2012 Oct 20;30(30):3655–6.
401 20. Heinrich KM., Patel PM., O'Neal JL., Heinrich BS. High-intensity compared to
402 moderate-intensity training for exercise initiation, enjoyment, adherence, and intentions: an
403 intervention study. BMC public health. 2014;14:789.
404 21. Khanna N, Nesbitt L, Roghmann M-C, Tacket C. Translation of clinical research into
405 practice: defining the clinician scientist. Fam Med. 2009 Jun;41(6):440–3.
406 22. Esculier J-F, Barton C, Whiteley R, Napier C. Involving clinicians in sports medicine

and physiotherapy research: "design thinking" to help bridge gaps between practice and evidence. Br J Sports Med. 2018 Oct 27;

23. Glassman G. What is CrossFit? The Crossfit Journal 2002. october 2002.

24. Claudino JG, Gabbett TJ, Bourgeois F, Souza H de S, Miranda RC, Mezêncio B, et al. CrossFit Overview: Systematic Review and Meta-analysis. Sports Med Open. 2018 Feb 26;4(1):11.

25. What Is Fitness? [Internet]. [cited 2018 Oct 24]. Available from: https://journal.crossfit.com/article/what-is-fitness

26. Luckett T, King MT, Butow PN, Oguchi M, Rankin N, Price MA, et al. Choosing between the EORTC QLQ-C30 and FACT-G for measuring health-related quality of life in cancer clinical research: issues, evidence and recommendations. Ann Oncol. 2011 Oct;22(10):2179–90.

27. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst. 1993 Mar 3;85(5):365–76.

28. Fayers P. EORTC QLQ-C30 Scoring Manual The EORTC QLQ-C30. 2001:1–67.

29. Godin G, Shephard RJ. A simple method to assess exercise behavior in the community. Can J Appl Sport Sci. 1985 Sep;10(3):141–6.

30. Jacobs DR, Ainsworth BE, Hartman TJ, Leon AS. A simultaneous evaluation of 10 commonly used physical activity questionnaires. Med Sci Sports Exerc. 1993 Jan;25(1):81–91.

Appendices

Appendix 1

Information concerning participation in a scientific research study

Trial title:
High Intensity Functional Training in the rehabilitation of cancer survivors – A pragmatic Intervention Study

We would like to ask you, if you would like to participate in a trial carried out at the Centre for Cancer and Health Copenhagen. The research trial is conducted by the University of Copenhagen and physiotherapist Andreas Lund Hessner.

Before you decide, whether you want to participate, you have to fully understand what the purpose of the study and why it is being conducted. Therefore, we would like to ask you to read this participant information thoroughly.
If you decide to participate in this study, we would like to ask you to sign a written consent statement. We would like to remind you that you are allowed time to consider before you decide whether you want to sign the written consent statement.
Participation in this study is voluntary. At any time, and without reason you have the right to withdraw you consent. Withdrawing from participation in this study will not have any consequences for your further treatment and rehabilitation.

Purpose

The purpose of this study is to investigate, whether 16 weeks of High intensity functional training improves the health-related quality of health in cancer survivors.

There is only one intervention group in this study and no control-group. There is therefore no randomization, and thus, all participants will complete 16 weeks of CrossFit-based exercise supervised by physiotherapists. CrossFit is a strength and conditioning program, that incorporates different exercise with both free weights and bodyweight movements.

Plan for study period

With your consent you agree to participate in 16-week weeks of group-based exercise including two weekly exercise sessions.
Prior to starting the intervention, we are going to ask you to complete a questionnaire with questions concerning cancer treatment, symptoms and physical activity level.
Immediately following 16-week intervention period you will receive another questionnaire. Three and 12 months following completion of the intervention period we will ask you to complete two identical questionnaires.
Following completion, the results of this trial will be published in scientific journals and will be presented at national medical conferences. All your personal information in this study is anonymised.

Your health information

All outcome in this study is going to be collected through questionnaires. This means that we will only collect information about you through these electronic questionnaires. Thus, there will not be collected information about you or your health from medical records of any kind.

If you consent to participate in this study, we will ask you for your e-mail address and as previously stated you will be asked to complete a total of four questionnaires. If you consent to participate we will in within the next two days send you the baseline questionnaire electronically.
We ask you to complete this questionnaire before your first High intensity functional training session in the intervention.

Relevance and benefits of the study

You will contribute to new knowledge and insights concerning the physical rehabilitation of people living with cancer, including the types of exercise, that might be beneficial for cancer survivors.

Potential side-effects, risks and complications

	Non serious potential side-effects	Serious	Long term risks
Side-effects	Muscle and joint pain Potential passing discomfort during the exercise sessions such as shortness of breath or dizzyness	None	None

There may occur risks associated with this study, that we do not yet know about. We ask you to notify us, if you are to experience any health problems or concerns, during your participation in the study.

Exclusion or interruption of study

If the health personnel at Centre for Cancer and Health Copenhagen assess that there may be health circumstances, which may imply that your continuation in this study may be associated with any type of risk, your participation in this study will be terminated. In this case the health personal will assist you in finding the best course of action.

Information about economic/financial conditions

No financial benefits are associated with your participation in this study.

Access to study results

One peer reviewed article will be published in a scientific journal, during the fall of 2020.
The results of this study will upon publication be communicated to various media and through the website of Centre for Cancer and health Copenhagen.
We hope that you through this information have received adequate insights into what it entails to participate in this study, and that you feel appropriately informed to make the decision whether to participate. We ask you to read the attached amendment concerning ”subjects rights in health scientific research projects”.
If you would like more information about the study, we recommend you to contact project leader

Andreas Lund Hessner
E-Mail: hessnerfysioterapi@gmail.com
Telephone: 51964161

Best regards,
Andreas Lund Hessner, PT, MSc.