

# Evaluation of an extended maintenance intervention on life satisfaction and BMI among 7-14-year-old children following a stay at a residential health camp in Denmark

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<b>Registration date</b> 16/05/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/09/2023	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Current plain English summary as of 14/06/2021:

### Background and study aims

For more than 100 years the private organization 'Julemærkefonden' has helped vulnerable children in Denmark, offering a ten week stay at one of their homes. In recent years the focus has been on well-being and overweight. 'Julemærkefonden' currently helps about 1000 children each year. The stay focuses on social relations, self-efficacy, self-esteem and healthy habits such as healthy food and physical activity.

The children apply for a stay themselves with help from their family, school and general practitioner. A doctor related to 'Julemærkefonden' reads the application and refers the child to the home, if the doctor believes the child will benefit from a stay.

Over the years 'Julemærkefonden' has been praised for doing a meaningful and important effort for vulnerable children in Denmark, but voices have also criticized that the efforts did not last after the children returned to their home environments. After a 10-week stay at a health camp we know that the children have higher life satisfaction and have a lower BMI. This effect wears off over time. This has never been documented.

To meet this criticism and because 'Julemærkefonden' wants to help the children both immediately but also in the long run, a new extended maintenance intervention has been developed at one of the health camps 'Lilkeborg'. With this new intervention, it is the intention to support the child back into its home environment after a 10-week stay. This study aims to evaluate this new intervention.

### Who can participate?

Children 7-14 years old who have participated in a 10-week camp focusing on lifestyle and well-being at one of the participating residential children's homes (Julemærkehjem).

### What does the study involve?

The study is an external evaluation of a quasi-experiment: the extended maintenance

intervention. It involves a total of five questionnaires for children participating in the 10-week health camp and receiving either the extended or the standard maintenance intervention. The extended maintenance intervention has been going on at Lilkeborg since 2018 for the 10 allocated municipalities. The standard maintenance intervention in its present form has been going on since 2015 after a stay at all of the homes. The study compares the extended maintenance to standard maintenance at all five camps and also just the Lilkeborg health camp.

What are the possible benefits and risks of participating?

Benefits would be maintaining better life satisfaction and BMI. Risks are too much focus on well being and BMI which can be hard if the child is not doing good.

Where is the study run from?

The intervention is run by the private fund 'Julemærkefonden' at the Lilkeborg home.

When is the study starting and how long is it expected to run for?

May 2019 to September 2022

Who is funding the study?

The Lilkeborg Foundation (Lilkeborg Fonden), Denmark and University of Southern Denmark

Who is the main contact?

Mette Kristoffersen, mekri@sdu.dk

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Previous plain English summary:

Background and study aims

For more than 100 years the private organization 'Julemærkefonden' has helped vulnerable children in Denmark, offering a ten week stay at one of their homes. In recent years the focus has been on well-being and overweight. 'Julemærkefonden' currently helps about 1000 children each year. The stay focuses on social relations, self-efficacy, self-esteem and healthy habits such as healthy food and physical activity.

The children apply for a stay themselves with help from their family, school and general practitioner. A doctor related to 'Julemærkefonden' reads the application and refers the child to the home, if the doctor believes the child will benefit from a stay.

Over the years 'Julemærkefonden' has been praised for doing a meaningful and important effort for vulnerable children in Denmark, but voices have also criticized that the efforts did not last after the children returned to their home environments. After a 10-week stay at a health camp we know that the children have higher life satisfaction and have a lower BMI. This effect wears off over time. This has never been documented.

To meet this criticism and because 'Julemærkefonden' wants to help the children both immediately but also in the long run, a new home- and community-based intervention has been developed at one of the homes 'Lilkeborg'. With this new intervention, it is the intention to support the child back into its home environment after a 10-week stay. This study aims to evaluate this new intervention.

Who can participate?

Children 7-14 years old who have participated in a 10-week camp focusing on lifestyle and well-being at one of the participating residential children's homes (Julemærkehjem).

### What does the study involve?

The study is an external evaluation of a natural experiment: the home-based extended follow-up. It involves a total of five questionnaires for children participating in the 10-week health camp and receiving either the extended or the regular follow-up. The extended follow-up has been going on at Lilkeborg for 1 - 5 years for the 10 allocated municipalities. The regular follow-up in its present form has been going on since 2015 after a stay at all of the homes. The study compares the extended follow-up to regular follow-up at Lilkeborg and regular follow-up at the other four homes.

### What are the possible benefits and risks of participating?

Benefits would be maintaining better life satisfaction and BMI. Risks are too much focus on well being and BMI which can be hard if the child is not doing good.

### Where is the study run from?

The intervention is run by the private fund 'Julemærkefonden' at the Lilkeborg home.

### When is the study starting and how long is it expected to run for?

May 2019 to May 2022 (updated 21/10/2020, previously: May 2020)

### Who is funding the study?

The Lilkeborg Foundation (Lilkeborg Fonden), Denmark

### Who is the main contact?

Mette Kristoffersen, mekri@si-folkesundhed.dk

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Mette Kristoffersen

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

10.142

## **Study information**

### **Scientific Title**

Does a 10-week home-based booster intervention maintain change in 7-14-year-old's life satisfaction after a health camp compared to no-intervention control – a non-randomized trial

### **Study objectives**

Current study hypothesis as of 14/06/2021:

A maintenance intervention supporting these children back into their home environment will improve the long-term outcome of the health camps measured by life satisfaction and BMI.

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Previous study hypothesis:

An intervention supporting these children back into their home environment will improve the long-term outcome of the health camps measured by life satisfaction and BMI.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

According to Danish law an ethics approval is not needed in observational studies. We comply with all Danish legislation in this field.

### **Study design**

Interventional controlled trial - quasi-experiment

### **Primary study design**

Interventional

### **Study type(s)**

Quality of life

### **Health condition(s) or problem(s) studied**

Quality of life

### **Interventions**

Current interventions as of 14/06/2021:

The extended maintenance intervention is carried out by a intervention coordinator assigned to the child. The intervention coordinator focusses on the individual child's needs, but the intervention always includes home visits and often also network meetings and conversations

with the child. The intervention focuses on supporting exercise habits, dietary habits, social network, family culture and structure, coping strategies, leisure time and communities, school life and the general well-being of the child.

Two control groups are allocated. Control group 1 includes children from the Liljeborg health camp along with the four other health camps receiving the standard maintenance intervention. Control group 2 is only children from the Liljeborg health camp allocated to the standard maintenance intervention.

In the intervention group, one of the four intervention coordinators from Liljeborg is allocated to the involved child. The intervention is needs-based and therefore flexible but encompasses e.g. home visits, school visits, coordination with stakeholders from the municipality, network meetings across settings among other things. They use a self-developed 'life satisfaction compass' with eight focus areas: exercise habits, dietary habits, social network, family culture and structure, coping strategies, leisure time and communities, school life and the general wellbeing of the child to find out which areas the maintenance intervention should focus on.

In the standard maintenance (13 of 23 municipalities, Region of Zealand) the children are allocated to one of four intervention coordinators. They are contacted after the stay by telephone and the coordinator help the child and family with smaller, specific things if needed or help the family address their concern e.g. to the municipality.

This study includes a process and effect evaluation of extended maintenance intervention. I have developed a questionnaire which will be distributed to the children and their parents at all five homes before the initiation of the 10-week stay at health camp after their stay at the home, four weeks after they come home, three months after returning home which is two weeks after the finalization of the follow-up intervention and one year after they get home from their stay. For the effect evaluation, the primary outcome is life satisfaction (Cantril ladder) and the secondary outcome is BMI.

Individuals are allocated to Intervention vs control individuals based on home municipality.

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Previous interventions:

The home- and community-based intervention consists of 30 hours of support from a follow-up coordinator allocated to each child in the intervention group. The hours are spent focusing on the individual child's needs, but the intervention always includes home visits. The intervention focuses on supporting exercise habits, dietary habits, social network, family culture and structure, coping strategies, leisure time and communities, school life and the general well-being of the child.

Two control groups are allocated. Control group 1: individuals from the same camp but without home intervention, Control group 2 from a comparable, but different camp and without home-based intervention following the camp.

In the intervention group, one of the four follow-up coordinators from Liljeborg is allocated to the involved child. The intervention allocates 30 hours per child distributed over 10 weeks. The intervention is needs-based and therefore flexible but encompasses e.g. home visits, school visits, coordination with resource people from the municipality, cross-disciplinary meetings

across settings among other things. They use a self-developed 'well-being-compass' with eight focus areas: exercise habits, dietary habits, social network, family culture and structure, coping strategies, leisure time and communities, school life and the general well-being of the child to find out which areas the home-based intervention should focus on.

In the regular follow-up (13 of 23 municipalities) the children are allocated to one of four follow-up coordinators. They are contacted after the stay by telephone and the coordinator help the child and family with smaller, specific things if needed or help the family address their concern e. g. to the municipality.

This study includes a process and effect evaluation of the home and community-based extended follow-up intervention. I have developed a questionnaire which will be distributed to the children and their parents at all five homes before the initiation of the 10-week stay at a the home, after their stay at the home, four weeks after they come home, 12 weeks after they come home which is two weeks after the finalization of the follow-up intervention and 13 months after they get home from their stay. For the effect evaluation, the primary outcome is life satisfaction (Cantril ladder) and the secondary outcome is BMI.

Individuals are allocated to Intervention vs control individuals based on home municipality.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Current primary outcome measure as of 14/06/2021:

Life satisfaction in children 7-14 years old, measured by the Cantril ladder at the following points:

1. First day of health camp
2. The last day of the health camp
3. Three months after the health camp
4. One year after the health camp

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Previous primary outcome measure:

Life satisfaction in children 7-15 years old, measured by the Cantril ladder at the following points:

1. Two - five weeks before the 10-weeks health camp
2. The last day of the health camp
3. Three months after the health camp
4. 12 - 13 months after the health camp

### **Key secondary outcome(s)**

Current secondary outcome measures as of 14/06/2021:

1. BMI measured at the health camp by the personnel on their weight and self-reported through questionnaires at the beginning of 10-week health camp, end of 10-week health camp, 3 months and 1 year after health camp (self-reported due to COVID-19)

Also collected at baseline, end of stay at home, three months after health camp and 1 year after health camp:

1. Self-efficacy (HBSC questionnaire, children)
2. Self-esteem (HBSC questionnaire, children)

3. Social relations (HBSC questionnaire, children)
  4. Health promoting behavior (HBSC questionnaire and developed specifically for the project, children)
  5. School satisfaction (HBSC questionnaire and developed specifically for the project, children)
  6. Body satisfaction (HBSC questionnaire /The Danish National Youth Study, children)
  7. Parental health promoting behavior (modified HBSC questionnaire and developed specifically for the project, parents)
  8. Parental self-efficacy (modified from the HBSC questionnaire, parents)
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Previous secondary outcome measures as of 28/05/2021:

1. BMI measured at the health camp by the personnel on their weight and self-reported through questionnaires at the beginning of 10-week health camp, end of 10-week health camp, 3 months and 1 year after health camp (self-reported due to COVID-19)

Also collected at baseline, end of stay at home, after follow-up intervention and 1 year after the stay:

2. Self-efficacy (HBSC questionnaire, children)
  3. Self-esteem (HBSC questionnaire, children)
  4. Social relations (HBSC questionnaire, children)
  5. Health promoting behavior (HBSC questionnaire and developed specifically for the project, children)
  6. School satisfaction (HBSC questionnaire and developed specifically for the project, children)
  7. Body satisfaction (HBSC questionnaire /The Danish National Youth Study, children)
  8. Parental health promoting behavior (modified HBSC questionnaire and developed specifically for the project, parents)
  9. Parental self-efficacy (modified from the HBSC questionnaire, parents)
  10. Cooperation between family, municipality and school (developed specifically for the project, follow-up coordinators)
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Previous secondary outcome measures from 18/10/2019 to 28/05/2021:

1. BMI measured at the health camp by the personnel on their weight and self-reported through questionnaires at the beginning of 10-week health camp, end of 10-week health camp, three months after health camp (self-reported), Liljeborg: 13 months after. The remaining four homes 12 months after (self-reported).

Also collected at baseline, end of stay at home, after follow-up intervention and one year after the stay:

2. Self-efficacy (HBSC questionnaire, children)
3. Self-esteem (HBSC questionnaire, children)
4. Social relations (HBSC questionnaire, children)
5. Health promoting behavior (HBSC questionnaire and developed specifically for the project, children)
6. School satisfaction (HBSC questionnaire and developed specifically for the project, children)
7. Body satisfaction (HBSC questionnaire /The Danish National Youth Study, children)
8. Parental health promoting behavior (modified HBSC questionnaire and developed specifically for the project, parents)
9. Parental self-efficacy (modified from the HBSC questionnaire, parents)
10. Cooperation between family, municipality and school (developed specifically for the project, follow-up coordinators)

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Original secondary outcome measures:

BMI measured at the health camp by the personnel on their weight and self-reported through questionnaires at the following time points:

- i. Beginning of 10-week health camp
- ii. End of 10-week health camp
- iii. Three months after health camp (self-reported)
- iv. Liljeborg: 13 months after. The remaining four homes 12 months after (self-reported)

### **Completion date**

15/08/2022

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 11/10/2022:

1. Age 7-14 years
2. Applied for and showed up on the first day at camp
3. Completed at least age and gender in the baseline survey

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Previous inclusion criteria as of 14/06/2021:

1. Age 7 - 14 years
2. Participating in a 10-week camp focusing on lifestyle and well-being. The children have applied for the camp themselves together with their families and have been found to meet the inclusion criteria for the camp which are low quality of life with e.g. low self-esteem, bullying, few or no friends, social problems or overweight.

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Previous inclusion criteria:

1. Age 7-15 years
2. Participating in a 10-week camp focusing on lifestyle and well-being. The children have applied for the camp themselves together with their families and have been found to meet the inclusion criteria for the camp which are low quality of life with e.g. low self-esteem, bullying, few or no friends, social problems or overweight.

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Child

**Lower age limit**

7 years

**Upper age limit**

14 years

**Sex**

All

**Total final enrolment**

1036

**Key exclusion criteria**

Current exclusion criteria as of 11/10/2022:

1. Not eligible for a stay at the camp e.g. children with severe psychiatric diagnoses or behavioural disorders.
2. No-show at health camp
3. Did not complete age/gender in baseline survey

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Previous exclusion criteria:

1. Not eligible for a stay at the camp e.g. children with severe psychiatric diagnoses or behavioural disorders.

**Date of first enrolment**

02/09/2019

**Date of final enrolment**

18/06/2021

## **Locations**

**Countries of recruitment**

Denmark

**Study participating centre**

**Julemærkehjemmet Liljeborg**

Baldersvej 3

Roskilde

Denmark

4000

**Study participating centre**  
**Julemærkehjemmet Hobro**  
Amerikavej 40  
Hobro  
Denmark  
9500

**Study participating centre**  
**Julemærkehjemmet Fjordmark**  
Fjordvejen 20  
Kollund  
Kruså  
Denmark  
6340

**Study participating centre**  
**Julemærkehjemmet Kildemose**  
Kildemosevej 15  
Ølsted  
Denmark  
3310

**Study participating centre**  
**Julemærkehjemmet Skælskør**  
Møllebakken 5  
Skælskør  
Denmark  
4230

## **Sponsor information**

**Organisation**  
National Institute of Public Health

**ROR**  
<https://ror.org/012bzsw43>

## **Funder(s)**

## Funder type

Charity

## Funder Name

Liljeborg Foundation (Liljeborg Fonden)

# Results and Publications

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		23/11/2021	14/12/2021	Yes	No