



Barn- och ungdomspsykiatriska kliniken

For you as a patient – research person information youth 13-14 years

Request to participate in the study "Randomised study comparing physical exercise in groups with recreational activity in groups for adolescents with depression"

Why do we want to do the study?

CAMHS now has a project in Halmstad, Stockholm, Kungsbacka and Lund with physical training or leisure activity in groups for young people with depression. We have already tried to treat young people who have been depressed for a long time with group training at a small gym. Most people got better in their depression but also contacts with friend and school improved. We don't know if it was the training itself or meeting and making something up with others that gave the effect. Now we want to compare the same physical training in groups with instead meeting in groups and playing games.

Who can participate?

Those who have been diagnosed with depression, do not yet exercise regularly and have not already gotten well or clearly better from the depression.

How does the study work?

The fact that the study is randomized means that you are drawn to either start working out in a group at the gym or to start meeting in groups to play games for twelve weeks. After the 12 weeks, those who have been drawn to play will have the opportunity to participate in the training in exactly the same way as the group that was originally drawn to training.

What happens before the group activities start?

If you're interested in participating, meet your local monitor (name here) to find out more. If you want to participate in the study, you will see a doctor for a simple medical examination, an assessment of depression and questions about other mental disorders, fill out a form about depression and provide a blood test. Then you get to test fitness and strength. The fitness is tested on a stationary exercise bike. You are allowed to cycle while your heart rate is measured, but the effort is moderate. You will also have to answer questions about depression and how it affects you via video calls on your mobile phone. That interview is being recorded. You then need to have a bankID installed on your phone or borrow your parent's phone with bankID for that moment.

Postadress: CAMHS, HSH, 30185 Halmstad **Besöksadress:** Vindrosvägen 4 **Tfn:** 035-13 17 61 **Fax:** 035-12 82 07
E-post: hakan.jarbin@regionhalland.se **Webb:** www.regionhalland.se **Org.nr:** 232100-0115



How does the treatment start?

After that, you will be drawn to either start with a playing group or with a training group. The training takes place at a small gym at Söndrumsvägen 29 at Rotorp and group leisure activities take place at CAMHS' premises at Vindrosvägen 4 in Halmstad. (The correct location/address of the other centres is inserted). There will be three group trainings or group activities at 15:30 for 60 minutes each week for 12 weeks. The groups start in February 2022 and the last time is in May 2022. (Exact dates will be inserted and may differ slightly between centers). Groups will also start in February 2023 and the last time is in May 2023. During the training period, you get to meet your PT twice to talk about your training. Every other week, you are asked to fill in questions about depression during both the training and leisure period.

What happens after treatment?

After 12 weeks of training or leisure activity, your fitness and strength, blood sampling and interview via mobile phone for symptoms of depression are checked. Then you will also be interviewed via your mobile phone about how you have experienced the training or leisure activities.

After another 12 weeks, you will be interviewed again via mobile phone about symptoms of depression. If you first played games, you can then start training in a group.

One year after starting group activity in the study, your fitness and strength are checked, blood samples are taken and interviewed via mobile phone about symptoms of depression. Then you will also be interviewed via mobile phone about how you experienced the training and leisure activities.

How do parents participate?

Your parents may need to help so that you can get to physical tests, blood tests and doctor's appointments and to the training sessions or group of games. A parent will also be asked to fill in questions at the start of treatment, after 12 and 26 weeks and a year later. The questions are about whether they needed to be free because of your troubles for visits to CAMHS and how much you have been able to be at school. One of your parents is interviewed after the group activity and after a year about their view of what the activity has meant.

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Voluntarism

It is completely voluntary to participate and you can decline even if your parents want you to join. You can cancel at any time without affecting your treatment at CAMHS. You have the right to have all data and recorded interviews deleted as well as your blood samples discarded. You can also get other treatment, but during the training period you should not go to regular therapy sessions or change your medication yourself. If you get worse, you may see a doctor to get medication or other treatment.

What are the risks and benefits?

Physical tests and blood tests can be unpleasant. The training is done with a good PT so the risk of injury is small and the study is an opportunity to get started. If you continue to exercise after the study, you may not have to have another depression instead. Exercise also generally makes you healthier. It can also be good and counteract depression to make up stuff like games with others your age. If you feel significantly worse during the study, we will arrange for you to see a doctor quickly. You then tell the CAMHS employee who leads the group or asks your parents to do so. We can also see if your self-assessment has clearly deteriorated and then contact you and hear about the situation.

Data, sample management and privacy

The study includes filling out questionnaires before and after three months of group activity and one year later. You also fill out a questionnaire on your mobile every other week during the training/gaming period and every month for the rest of the year. Reminders come with automatic text messages. Everything we learn about you is treated with confidentiality. No outsider can access the answers so they can be connected to you. We store recorded interviews on a hard drive in a locked cabinet at CAMHS in Halmstad. The code key is available to monitor Henriette Nielsen and project manager Håkan Jarbin. The coded interview is printed by Secretary Anna Havner and then kept in a locked locker for ten years. These printouts are available to the research group, which will analyse the texts and encode the information based on a qualitative methodology. The group consists of Associate Professor Ingrid Larsson from Halmstad University and Doctoral Students Rebecca Mortazavi, CAMHS Halland and Rebecca Grudin, Karolinska Institutet. Blood samples stored pseudonymized (encoded) in a biobank in Region Halland to be investigated later for substances in the blood that may affect depression. You have the right to say no to the samples being saved. If you agree to the samples being saved, you have the right to later

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withdraw (undo) that consent. In this case, your samples will be discarded or de-identified. If you wish to regret consent, please contact Håkan Jarbin.

Region Halland is responsible for ensuring that your personal data is given the same protection as regular medical records. According to the EU Data Protection Regulation, you have the right to access the data about you handled in the study without paying, and if necessary to have any errors corrected. You can also request that information about you be deleted and that the processing of your personal data be restricted. If you would like to access the information, please contact Håkan Jarbin, CAMHS, Vindrosvägen 4, 30290 Halmstad, +46 (0)70-9162801 (secr) or via hakan.jarbin@regionhalland.se. Data Protection Officers can be reached at Region Halland, Operational Board Psychiatry 035-134800 or dataskydd@regionhalland.se. If you are dissatisfied with how your personal data is processed, you have the right to lodge a complaint with the Swedish Data Protection Authority, which is the supervisory authority. The application is approved by the Ethical Review Authority, the record number for the examination at the Ethical Review Authority is 2021 - 05307 - 01.

Compensation

You get an encouragement with a gift card of SEK 500 for each of the two occasions with interviews about the goal and about what you think about the group activity, physical tests and blood sampling that you do after the training period.

Halland, September 2021

Håkan Jarbin,

PhD, medical head and principal investigator

hakan.jarbin@regionhalland.se mobile phone 0706778006

Adress: Region Halland, Box 517, 301 80 Halmstad . **Besöksadress:** Södra vägen 9 . **Tfn:** 035-13 48 00 . **Fax:** 035-13 54 44
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For you as a patient – research person information youth 15-17 years

Request to participate in the study "Randomised study comparing physical exercise in groups with recreational activity in groups for adolescents with depression"

Why do we want to do the study?

CAMHS now has a project in Halmstad, Stockholm, Kungsbacka and Lund with physical training or leisure activity in groups for young people with depression. We have already tried to treat young people who have been depressed for a long time with group training at a small gym. Most people got better in their depression but also self-image, relationships and school results improved. We don't know if it was the training itself or meeting and making something up with others that gave the effect. Now we want to compare the same physical training in groups with instead meeting in groups and playing games.

Who can participate?

Those who have been diagnosed with depression, do not yet exercise regularly and have not already gotten well or clearly better from the depression.

How does the study work?

The fact that the study is randomised means that you are drawn to either start working out in a group at the gym or to start meeting in groups to play games for twelve weeks. After the 12 weeks, those who have been drawn to play will have the opportunity to participate in the training in exactly the same way as the group that was originally drawn to training.

What happens before the group activities start?

If you are interested in participating, you will meet the local monitor (name here) to find out more. If you want to participate in the study, you will see a doctor for a simple medical examination, an assessment of depression and questions about other mental disorders, fill out a form about depression and provide a blood test. Then you get to test fitness and strength. The fitness test is a so-called submaximal test on a stationary bike. You are allowed to cycle while your heart rate is measured, but the effort is moderate. You will also have to answer questions about depression and how it affects you via video calls on your

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mobile phone. That interview is being recorded. You then need to have a bankID installed on your phone or borrow your parent's phone with bankID for that moment.

How does the treatment start?

After that, you will be drawn to either start with a playing group or with a training group. The training takes place at a small gym at Söndrumsvägen 29 at Rotorp and group leisure activities take place at CAMHS's premises at Vindrosvägen 4 in Halmstad. (The correct location/address of the other centres is inserted after the contract is completed there). There will be three group activities at 3.30pm in 60 minutes each week for 12 weeks. The groups start in February 2022 and the last time is in May 2022. (Exact dates will be inserted and may differ slightly between centers) Groups will also start in February 2023 and the last time is in May 2023. During the training period, you get to meet your PT twice to talk about your training. Every other week, you are asked to fill in questions about depression during both the training and leisure period.

What happens after treatment?

After 12 weeks of training or leisure activity, your fitness and strength, blood sampling and interview via mobile phone are checked for symptoms of depression. Then you will also be interviewed via your mobile phone about how you have experienced the training or leisure activities. After another 12 weeks, you will be interviewed again via mobile phone about symptoms of depression.

If you first played games, you can then start training in a group.

One year after starting group activity in the study, your fitness and strength are checked, blood samples are taken and interviewed via mobile phone about symptoms of depression. Then you will also be interviewed via mobile phone about how you experienced the training and leisure activities. One year after starting group activity in the study, your fitness and strength are checked, blood samples are taken and interviewed via mobile phone about symptoms of depression. Then you will also be interviewed via mobile phone about how you experienced the training and leisure activities.

How do parents participate?

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Your parents may need to help so that you can get to physical tests, blood tests and doctor's appointments and to the training sessions or group of games. A parent will also be allowed to fill in questions at the start of treatment, after 12 and 26 weeks and a year later. The questions are about whether they needed to be free because of your troubles for visits to CAMHS and how much you have been able to be at school. One of your parents is interviewed after the group activity and after a year about their view of what the activity has meant.

Voluntarism

It is completely voluntary to participate and you can decline even if your parents want you to join. You can cancel at any time without affecting your treatment at CAMHS. You have the right to have all data and recorded interviews deleted as well as your blood samples discarded. You can also get other treatment, but during the training period you should not go to regular consultations or change your medication yourself. If you get worse, you may see a doctor to get medication or other treatment.

What are the risks and benefits?

Physical tests and blood tests can be unpleasant. The training is done with a good PT so the risk of injury is small and the study is a nice opportunity to get started. If your training continues after the study, you may not have to have another depression instead. Exercise also generally makes you healthier. It can also be good and counteract depression to come out and make up stuff like games with others your age. If you feel significantly worse during the study, we will arrange a quick medical assessment. You will then contact the CAMHS employee who is leading the group. We can also see if the self-assessment has clearly deteriorated and then contact you and hear about the situation.

Data, sample management and privacy

The study includes filling out questionnaires before and after three months of group activity and one year later. You also fill out a questionnaire on your mobile every other week during the training/gaming period and every month for the rest of the year. Reminders come with automatic text messages. Everything we learn about you is treated with confidentiality. No outsider can access the answers so they can be connected to you. We store recorded

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interviews on a hard drive in a locked cabinet at CAMHS in Halmstad. The code key is available to monitor Henriette Nielsen and principal investigator Håkan Jarbin. The coded interview is typed by secretary Anna Havner and then kept in a locked locker for ten years. These printouts are available to the research group, which will analyse the texts and encode the information based on a qualitative methodology. The group consists of Associate Professor Ingrid Larsson from Halmstad University and Doctoral Students Rebecca Mortazavi, CAMHS Halland and Rebecca Grudin, Karolinska Institutet. The blood samples are stored pseudonymized (coded) at the biobank within Region Halland and later analyzed for biomarkers i.e. substances in the blood that can affect depression. You have the right to say no to the samples being saved. If you agree to the samples being saved, you have the right to later withdraw (undo) that consent. In this case, your samples will be discarded or de-identified. If you wish to regret consent, please contact Håkan Jarbin.

Region Halland is responsible for ensuring that your personal data is given the same protection as regular medical records. According to the EU Data Protection Regulation, you have the right to access the data about you handled in the study free of charge and, if necessary, to have any errors corrected. You can also request that data about you be deleted and that the processing of your personal data be restricted. If you want to access the data, please contact Håkan Jarbin, CAMHS, Vindrosvägen 4, 30290 Halmstad, 070-9162801 (secr) or via hakan.jarbin@regionhalland.se. Data Protection Officers can be reached at Region Halland, Operational Board Psychiatry 035-134800 or dataskydd@regionhalland.se. If you are dissatisfied with how your personal data is processed, you have the right to lodge a complaint with the Swedish Data Protection Authority, which is the supervisory authority. The application is approved by the Ethical Review Authority, the record number for the examination at the Ethical Review Authority is 2021 - 05307 - 01.

Compensation

You get an encouragement with a gift card with SEK 500 for each of the two occasions with interviews about the goal and about what you think about the group activity, physical tests and blood sampling that you do after the training period.

Halland in September 2021

Håkan Jarbin,

PhD, medical head and principal investigator

hakan.jarbin@regionhalland.se mobile phone 0706778006

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To guardians - research person information

Request to participate in the study "Randomized study comparing physical exercise in groups with recreational activity in groups for adolescents with depression"

Why do we want to carry out the study?

Within the framework of a multicenter study in Halmstad, Stockholm, Kungsbacka and Lund, physical training or leisure activity is offered in groups as a treatment for depression to young people 13-17 years of age. There is currently research to suggest that physical exercise has an effect comparable to conversational therapy or drug treatment. It is also known that social activation can be helpful in depression. We have conducted an open-label study in which 21 adolescents with persistent depression trained in groups. After treatment, depression but also self-image, relationships, school results and family life had improved, but we do not know if the social activity or exercise had an effect. In 2021, we also conducted a small pilot study where young people with depression either trained physically in groups or met to socialize and play games. With small improvements in the details of the study plan, we now want to take the next step and investigate whether physical exercise has an effect in addition to coming out and meeting other young people.

Target group

Participation in the study will be offered to young people who have been diagnosed with depression, do not yet exercise regularly and have not improved well or clearly after initial calls or other treatment at CAMHS.

How does the study work?

The fact that the study is randomised means that participants are drawn to either exercise in groups at a gym or to meet in groups to play games for twelve weeks. After the 12 weeks, those who were drawn for leisure activities will have the opportunity to participate in the physical training in exactly the same way as the group that was originally drawn to physical activity in a group. Those who were drawn for group training will not be offered extracurricular activities after completing training.

What happens before the group activities start?

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If your child is interested in participating, he/she and you will be invited to a meeting with the study's local monitor (name will be inserted later) for oral and written information about the study. Those who then agree to participate in the study then see a psychiatrist for an assessment of the diagnosis of depression and possibly other mental disorders. There will also be a simple medical examination and blood tests. The patient is allowed to fill out Self report questionnaires about symptoms. After that, there is the measurement of fitness and strength, blood sampling and an interview via mobile phone about the degree of symptoms of depression and how to manage to function in everyday life. That interview is being recorded. For security reasons, Region Halland's video calling platform Visiba care is used. Young people need to have bankID installed on their phone or to borrow a parent's phone with bankID.

How does the treatment start?

After that, you are drawn to either start with training or start with leisure activities. Both activities take place in groups with other adolescents with depression. For Halmstad, the training takes place at a small gym at Söndrumsvägen 29 at Rotorp and the leisure activity at CAMHS's premises at Vindrosvägen 4. (Location of other cities is added when contracts are signed). There will be three group trainings or group free time activities at 15:30 per week of 60 minutes with the first start February 2022 and then closure in May 2022 and starting February 2023 and then ending in May 2023 Each youth who trains will receive two individual conversations with PT for planning and monitoring the training. Forms about symptoms of depression and well-being are answered by youth via online link on the mobile phone every other week during both the training and leisure activity period.

What happens after treatment?

After 12 weeks of training or leisure activity, there is a renewed measurement of fitness and strength, blood sampling and interview via mobile phone about symptoms of depression. Then an interview of the youth is also conducted about how they have experienced the training or leisure activity. After another 12 weeks, a renewed interview takes place via mobile phone about symptoms of depression and questionnaires to parents about costs. Those who first had recreational activity in a group are then allowed to start with 12 weeks of training in a group and fill out forms about depression via mobile every two weeks.

How does the follow-up proceed up to one year after the start?

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Self report forms about symptoms of depression and well-being are answered by the youth on the mobile phone every month throughout the year. One year after the start, there is a renewed measurement of fitness, blood sampling and interview about depression and everyday function via mobile. Then a new interview of the youth will also be conducted about how they have experienced and been able to continue with the training.

How do parents participate?

Patients usually need support from parents to both get to and for the transport to the group activity on three occasions a week. Gradually, carpooling may be arranged for patients who have a similar itinerary to group activity. Parents need to participate in the diagnostic interview before the start of the study and be supportive so that the youth comes to the physical tests and blood tests. At the start of treatment, after 12 weeks, after 26 weeks and after one year via mobile phone, parents are offered to complete a questionnaire on health economics i.e. the presence of leave for the care of children, for visits to CAMHS and the current extent of schooling. Parents are offered to be interviewed via video link after group treatment and after one year about what group activity has meant and also to answer a survey question to what extent they have experienced any improvement in the well-being of their child.

Voluntarism

Participation is entirely voluntary. It is possible to discontinue group activities at any time without affecting other treatment. You also have the right to have all data and recorded interviews deleted and blood samples discarded. Patients have access to other treatment, but during the training period they should not go to regular conversations or change their medication themselves. Medication or adjusted medication may be offered in case of deterioration.

What are the risks?

There are few risks with the study. Measuring strength and fitness and blood sampling can cause slight discomfort at the moment. The training is done with close monitoring and thus little risk of injury. There are advantages to getting started with regular physical exercise under the supervision of a personal trainer. It increases the possibility of being free of depression. If exercise continues after the study, the risk of future episodes of depression may decrease. Exercise provides improved physical health. There are also advantages to

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participating in group leisure activities. Coming out and meeting other young people and participating in fun activities can counteract depression. If the patient should feel significantly worse during the course of the study, we will arrange a quick medical assessment. You then contact the CAMHS employee who leads the group. We can also see if the self-assessment has clearly deteriorated and then get in touch. During the course of the study, the usual patient insurance applies.

Data, sample management and privacy

The study includes filling out questionnaires before and after the group activity and one year after the start. Patients also complete a questionnaire every two weeks during the activity period and every month for the rest of the year. The questionnaires are filled in with a mobile phone and reminders come with automatic text messages. All data, such as social security numbers and questionnaire replies, are treated confidentially. Recorded interviews will be stored on a separate hard drive in a locked locker at the CAMHS clinic. The blood samples will be stored pseudonymized at the biobank within Region Halland (principal) within Halland Hospital, and later analyzed for inflammatory and neuroprotective biomarkers. You have the right to say no to the samples being saved. If you agree to the samples being saved, you have the right to later withdraw (undo) that consent. In this case, your child's samples will be discarded or de-identified. If you wish to regret consent, please contact Håkan Jarbin. The Ethical Review Authority has authorised the inclusion of the data collected in the study in a data-based research register. In the data register, the information is pseudonymized by a code, which is stored in a locked cabinet within CAMHS's premises at Vindrosvägen 4 in Halmstad. The code key is available to monitor Henriette Nielsen and project manager Håkan Jarbin. The coded interview is printed by Secretary Anna Havner and then kept in a locked locker for ten years. These printouts are available to the research group who will analyze the texts and encode the information based on a qualitative methodology. The group consists of Associate Professor Ingrid Larsson from Halmstad University and Doctoral Students Rebecca Mortazavi, CAMHS Halland and Rebecca Grudin, Karolinska Institutet. Thus, no outsider has the opportunity to access the answers in such a way that they can be linked to the person.

Region Halland is responsible for ensuring that personal data is given the same protection as ordinary medical records. According to the EU Data Protection Regulation, you have the right to access the data about your child handled in the study free of charge and, if necessary, to have any errors corrected. You can also request that data about your child be deleted and that the processing of your child's personal data be restricted. If you would like to access the

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Insurance and compensation

The usual patient insurance is valid for this study. There is no compensation for parents' or children's expenses for participation in the treatment, but the child receives an encouragement with a gift card of SEK 500 for each of the two occasions with physical tests, interview about symptoms and interview about how the group and the training have worked for them and blood sampling after the training period.

Halmstad in September 2021

Håkan Jarbin,
PhD, medical head and principal investigator
hakan.jarbin@regionhalland.se mobile phone 0706778006

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