The Effect of Two Different Interventions on Chronic Pain and Mental Health Symptoms among Syrian Refugees

Wegdan Hamed Nasser Hasha

Thesis for the degree of Philosophiae Doctor (PhD)
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1. SCIENTIFIC ENVIRONMENT

This research was carried out at the Department of Global Public Health and Primary Care, the University of Bergen, Faculty of Medicine. The project was funded by the Norwegian Research Council (BEHANDLING, 269835/H10).

Dr Esperanza Diaz, professor at the Department of Global Public Health and Primary Care, Faculty of Medicine at the University of Bergen, is the main supervisor, while Dr Bernadette Nirmal Kumar, professor at the Norwegian Institute of Public Health & Empower School of Health India, and Dr Lars Thore Fadnes, professor at the Department of Global Public Health and Primary Care, Faculty of Medicine at the University of Bergen, are the co-supervisors.

The CHART (Changing Health and health care needs Along the Syrian Refugees' Trajectories to Norway) study includes researchers from different professions and walks of life, including physicians, odontologists, psychologists and statisticians, healthcare professionals with expertise in physiotherapy and psychology, and representatives from the Syrian community as user representatives. The following institutions in Norway are represented in the study: Norwegian Institute of Public Health, Health services for refugees, asylum seekers and family reunification (Centre for Migration Health), Bergen municipality, Nygaard School, Integration Reception Centre, Kristiansand municipality and Norwegian Centre for Violence and Traumatic Stress Studies (NKVTS). The CHART-reference group includes international collaborators from the University of Bristol (United Kingdom), Irish College of General Practitioners (Ireland) and the migration health unit of The International Organization for Migration (IOM) in Belgium,

In addition to this PhD thesis, in which I assess the effect of two different interventions on chronic pain and mental health symptoms among Syrian refugees, several other PhD fellows and master's students have worked together in the CHART study. One PhD fellow has examined the burden of somatic and mental ill health as well as the risk

factors for disease among refugees; another PhD fellow has examined self-rated health, quality of life and the experience of access to healthcare services. In addition, three master's students have worked closely on the CHART study, one from the University of Bergen studying food insecurity and mental health, and two from the University of Oslo, one studying the use of medication and the other the use of translators in the interventions that I describe in this thesis.

2. ACKNOWLEDGEMENTS

It has been a long journey to this point and one which would not have been possible without the effort and support of so many people. I am deeply grateful to all those who have helped me along the way.

I have been blessed to have the best professors—Dr Esperanza Diaz, Dr Bernadette Kumar, and Dr Lars Thore Fadnes—all deeply committed to the welfare of migrants and fighting for their better health, both nationally and globally.

I thank Dr Diaz for her endless enthusiasm, determination, and devotion. She has both inspired me and stimulated my thoughts. The life of a PhD student is mainly a roller coaster, a time of desperation and triumph. I am grateful to her for being there for me at all times. In moments of despair and disappointment, she has inspired me and celebrated my triumphs, driving me to accomplish even greater goals.

My co-supervisors, Dr Kumar and Dr Lars T, have encouraged me to scale new heights and to not just be content with where I am academically. I greatly appreciate their feedback on the papers and thesis. I am most grateful to them for their willingness to make time, even in between busy schedules, for discussions.

I am especially grateful to Associate Professor Jannicke Igland for helping me with statistical analysis. I thank her for always being available for discussions relating to the thesis. I would also like to give my special thanks to two of my best colleagues and fellow PhD candidates Jasmin and Elisabeth. I appreciate you for sharing the PhD journey together with me.

The Department of Global Public Health and Primary Care is such a wonderful place to be. It has been a wonderful journey with valuable discussions, meetings, and celebrations at the department. I thank all my colleagues from the bottom of my heart for welcoming me, for their support and motivation, and for their insightful comments to this thesis. I am most grateful to Daniel Gundersen and Kirsti Nordstrand,

coordinators for PhD students at The Department of Global Public Health and Primary Care, for their support in practical matters such as planning research school meetings and sending reminders.

For researchers like me, the Norwegian Research School in General Practice (NAFALM) is such a productive place to learn, discuss and improve academically. I thank all the lecturers, particularly Professor Linn Gertz and Associate Professor Stefan Hjørleifsson, and my fellow students for their important educational meetings and discussions. I also extend a big thank you to the participants in the focus groups and the user representatives for their valuable time and for sharing their knowledge. I also thank physiotherapists Line Giusti and Rolf Vårdal, and Kaia Brun, a psychologist, at the Centre for Migration Health, Bergen municipality for their wonderful collaboration.

I thank all my friends for their encouragement and help, especially during tough and unproductive times.

Lastly, I am grateful and thankful to my family—my mother, my brothers (Majid and Mohammed), and my sisters (Donya, Ehab and Raghed)—for their unconditional love and support and trust in me, without which none of this would have been achievable. I would like to especially mention Geed, my lovely daughter; Ahmed, my friendly son; Faisal, my sweet baby; and last but not least, the dearest and sweetest person in my life, Alaa Assadi, my husband, for his positive support and motivation that has encouraged me to finish this job and change my life. This PhD would not have been possible without his encouragement.

3. ABBREVIATIONS

BBAT: Basic Body Awareness Therapy

BPI: Brief Pain Inventory

BPI-SF: Brief Pain Inventory-Short Form

CBT: cognitive-behavioural therapy

CHART: Changing Health and health care needs Along the Syrian Refugees' Trajectories to Norway

CONSORT: Checklist of information to include when reporting a randomized trial

CRIES-13: 13-item Children's Revised Impact of Event Scale

EMDR: Eye Movement Desensitization and Reprocessing

EWSQ: Exposure to War Stressors Questionnaire

GHQ-12: 12-item General Health Questionnaire

HUNT 3: The Nord-Trøndelag Health Study

IES-R 22: 22-item Impact of Event Scale-Revised

ITT: intention-to-treat

MBSR: mindfulness-based stress reduction

MBTR-R: Mindfulness-Based Trauma Recovery for Refugees (MBTR-R)

NET: Narrative Exposure Therapy

PAAI: Physiotherapy Activity and Awareness Intervention

PM+: Problem Management Plus

PTSD: post-traumatic stress disorder

Q0: Questionnaire 0

Q1: Questionnaire 1

RCT: Randomized Controlled Trial

SDQ: Strengths and Difficulties Questionnaire

SOC-13: 13-item Sense of Coherence Scale

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

TCM: Traditional Chinese medicine

TF-CBT: trauma-focused cognitive behavioural therapy

TRT: Teaching Recovery Techniques

UDI: The Norwegian Directorate of Immigration

UNHCR: United Nations High Commissioner for Refugees

UNRWA: United Nations Relief and Works Agency for Palestine Refugees in the Near East

URMs: Unaccompanied refugee minors

WHO-5: 5-item World Health Organization Well-being Index

4. SUMMARY

The main aim of this PhD project is to assess the effect of two different interventions among adult Syrian refugees suffering from pain and/or post-traumatic symptoms: (i) Physiotherapy Activity and Awareness Intervention (PAAI) in reducing pain disorders and mental health symptoms (if present), and (ii) a self-help group intervention using Teaching Recovery Techniques (TRT) to improve mental health and reduce pain (if present).

The interventions were adapted for our participants in cooperation with the municipality of Bergen, municipality of Fjell, the Centre for Crisis Psychology, and the users. Both treatments were tested using a randomized controlled trial (RCT) design implemented from August 2018 to December 2019. In addition, a qualitative assessment was performed through an embedded process evaluation and through personal interviews with participants after the completion of the interventions.

The first paper in this thesis is the study protocol for both interventions and it describes in detail the methodology used. The second paper presents, primarily, the effect of PAAI in reducing pain disorders and secondarily in improving general mental health among 101 Syrian refugees. Although PAAI had no effect on reducing either pain symptoms or improving mental health among refugees by intention-to-treat (ITT), this paper also includes the qualitative experiences among participants, including self-perceived benefits of the intervention and challenges/barriers to attending the intervention.

The third paper presents the effect of a self-help group using TRT to improve mental health and secondarily reduce the pain disorder among 76 adult Syrian refugees reporting mental health symptoms. Our study found that the self-help group intervention statistically improved general mental health among adults' refugees in ITT analysis measured by the 12-item General Health Questionnaire (GHQ-12). However, there was no effect of TRT on either mental health when measured by the 22-item Impact of Event Scale-Revised (IES-R 22) or on pain levels measured by the Brief Pain Inventory (BPI).

Our research contributes to the evidence base needed to develop focused and effective healthcare services for refugees and indicates that the tested interventions might have some positive effects but are generally not as effective as expected on the primary outcomes. Thus, further research on how to improve health among refugees is needed.

5. NORWEGIAN SUMMARY

Hovedmålet med dette Ph.d.-prosjektet var å vurdere effektene av to forskjellige intervensjoner blant voksne syriske flyktninger som lider av smerte og / eller posttraumatiske symptomer: (i) Physiotherapy Activity and Awareness Intervention (PAAI) for å redusere smerter og psykiske helseplager (hvis tilstede), og (ii) En selvhjelpsbasert gruppeintervensjon basert på Teaching Recovery Techniques (TRT) som gir verktøy for å håndtere traumerelaterte symptomer og plager for å forbedre mental helse og redusere smertesymptomer (hvis tilstede).

Intervensjonene ble tilpasset våre deltakere i samarbeid med Bergen kommune, Fjell kommune, Senter for krisepsykologi og brukerne. Begge behandlingene ble testet i en randomisert kontrollert studie gjennomført fra august 2018 til desember 2019 blant 101 syriske flyktninger. I tillegg ble kvalitative intervjuer utført som ledd i en prosessevaluering der personlige intervjuer med deltakerne ble gjennomført etter fullført intervensjon.

Den første delen i artikkelen er studieprotokollen for begge intervensjonene der metoden beskrives i detalj. Den andre delen presenterer først og fremst effekten av den gruppeintervensjonen med fysioterapi (PAAI) for å redusere smerter og for å forbedre den mentale helsen blant flyktningene. Selv om PAAI ikke viste noen effekt på å redusere verken smerter eller i å forbedre mental helse blant flyktninger, inkluderer denne artikkelen også de kvalitative opplevelsene blant deltakerne der det ble rapportert at mange opplevde fordeler med intervensjonen utover det som ble systematisk kartlagt, men også enkelte utfordringer i å delta på intervensjonen.

Den tredje delen i artikkelen presenterer effekten av en selvhjelpsgrupper som bruker TRT for å forbedre mental helse og redusere smerter blant 76 voksne syriske flyktninger med psykiske helseplager. Studien vår viste at selvhjelpsgruppene forbedret mental helse blant voksne flyktninger målt ved verktøyet GHQ-12. Imidlertid var det ingen

effekt av TRT på traumerelaterte symptomer målt ved IES-R-22 eller på smerter målt ved BPI.

Vår forskning tyder på at intervensjonene vi testet kan ha hatt enkelte positive helseeffekter, men var ikke fullt så effektive som antatt i å redusere smerter og traumerelaterte psykiske helseplager. Det er derfor behov for å utvikle flere verktøy for å bedre helse blant flyktninger.

6. ARABIC SUMMARY

ان الهدف الرئيسي لمشروع الدكتوراه هذا هو تقييم تاثير تدخلين مختلفين بين اللاجئين السوريين البالغين الذين يعانون من الالم و/ أو أعراض مابعد الصدمة ,وهذين التدخلين هما

. نشاط العلاج الطبيعي والتدخل التوعوي في الحد من اضطرابات الألم و اعراض الصحة العقلية إن وجدت

.التدخل الجماعي للمساعدة الذاتية باستخدام تقنيات التعافي التعليمية لتحسين الصحة العقلية وتقليل الألم إن وجد

تم التكيف لتنفيذ التدخلات للمشاركين لدينا بالتعاون مع بلدية بيرغن وبلدية فيال ومركز علم النفس للأزمات ومساعديين سوريين تم اختبار كلا العلاجين باستخدام تصميم التجربة العشوائية و تم تنفيذها من

أغسطس 2018 إلى ديسمبر 2019

بالإضافة إلى ذلك ، تم إجراء تقييم نوعي من خلال عملية تقييم مضمونة ومن خلال المقابلات الشخصية مع المشاركين بعد الانتهاء من التدخلات
الورقة الأولى في هذه الأطروحة هي بروتوكول الدراسة لكلا التدخلين

الورقة الثانية تعرض بشكل أساسي تأثير تدخل مجموعة العلاج الطبيعي في الحد من اضطرابات الألم وثانيًا في تحسين الصحة النفسية العامة بين 101 لاجئ سوري

على الرغم من أنه لم يكن لمجموعة العلاج الطبيعي أي تأثير على الحد من اضطراب الألم أو تحسين الصحة العقلية بين اللاجئين ، فإن هذه الورقة تتضمن أيضًا الخبرات النوعية بين المشاركين ، بما في ذلك الجودة والفوائد المدركة ذاتيًا للتدخل والتحديات/ العوائق التي تحول دون حضور التدخل

تعرض الورقة الثالثة تأثير مجموعة المساعدة الذاتية لتحسين الصحة العقلية وتقليل اضطراب الألم بشكل ثانوي بين 76 لاجئًا سوريًا

وجدت دراستنا أن تدخل مجموعة المساعدة الذاتية حسّن إحصائيًا الصحة النفسية العامة بين اللاجئين البالغين في تحليل المقاس بواسطة

GHQ-12

ومع ذلك ، لم يكن هناك تأثير لمجموعة المساعدة الذاتية على الصحة العقلية أو على مستويات الألم عند قياسها بواسطة IESR-22 و BPI

يساهم بحثنا في قاعدة الأدلة اللازمة لتطوير خدمات رعاية صحية مركزة وفعالة للاجئين ويشير إلى أن التدخلات المختبرة قد يكون لها بعض الآثار الإيجابية ولكنها عمومًا ليست فعالة كما هو متوقع على النتائج الأولية

وبالتالي ، هناك حاجة إلى مزيد من البحث حول كيفية تحسين الصحة بين اللاجئين .

7. List of Publications

Articles I-III

I. Hasha, W, Fadnes, LT, Igland, J, Vårdal, R, Giusti, LM, Strømme, EM, Younes, JH, Heltne, U, Kumar, B, and Diaz, E. (2019). Two interventions to treat pain disorders and post-traumatic symptoms among Syrian refugees: protocol for a randomized controlled trial. Published at BMC Trials 20:784 https://doi.org/10.1186/s13063-019-3919-x.

II. Hasha, W, Igland, J, Fadnes, LT, Kumar, B, Younes, JH Strømme, EM, Norstein EZ, Vårdal, R, and Diaz, E. (2020). The effect of a physiotherapy group intervention in reducing pain disorders and mental health symptoms among Syrian refugees. A Randomized Controlled Trial. The International Journal of Environmental Research and Public Health

III. Hasha, W, Igland, J, Fadnes, LT, Kumar, B, Heltne, U and Diaz, E. Effect of a self-help group intervention using teaching recovery techniques to improve mental health among Syrian refugees. A randomized controlled trial. The Journal of mental health

Submitted for publication

Note: I will refer to the articles as Paper I, II and III.

8. DEFINITIONS

Access to health services: ‘The timely use of personal health services to achieve the best health outcomes’(1).

Asylum seeker: A person leaving his or her country of origin, entering another country and applying for asylum in that country (foreign protection) (2).

Pain: ‘An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage’ as defined by The International Association for the Study of Pain (3).

Cultural sensitivity: The abilities that enable you to understand and learn about individuals whose cultural background is not the same as yours (4).

Health: The World Health Organization (WHO) defines health ‘as a state of complete physical, mental and social well-being and not only the absence of disease or infirmity’ (5).

Post-traumatic stress disorder (PTSD): A psychiatric disorder that can happen in persons that have experienced traumatic events such as a natural disaster, war, a major accident, a terrorist attack, or rape, or who have been threatened with death, sexual assault, or serious injury (6).

Refugee: The 1951 Refugee Convention describes a refugee as: ‘someone who is unable or unwilling to return to their country of origin owing to a well-founded fear of being persecuted for reasons of race, religion, nationality, membership of a particular social group, or political opinion’ (7).

Traumatized refugee: Refugees who have experienced stressful events and severe trauma, such as torture, war, living in refugee camps, losing loved ones, sexual abuse, political or religious violence, migration, and resettlement that causes them to flee (8).

Unaccompanied refugee (URMS): Refugee children under the age of 18 without a parent (9).

9. INTRODUCTION

9.1. REFUGEES

The movement of people from one place to another is called migration. The types of migration differ with regard to distance, duration and purpose. The variety and complexity of migration patterns involve individuals travelling long and short distances for temporary or permanent residence, within and across borders, and sometimes undertaking the same or different journeys many times. International migration can include both permanent and rural-to-urban migration at the same time. Depending on the wave and type of migration, the push-and-pull variables will differ in the time between the phases (10). **Figure 1** describes the phases of migration.

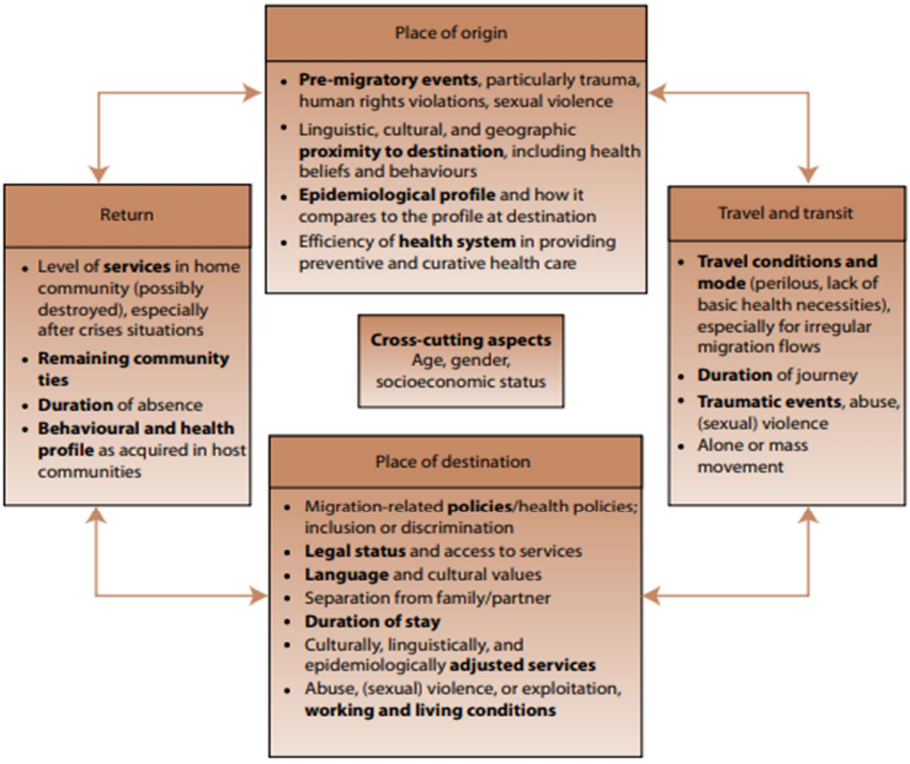

Figure 1: *The phases of migration in the migration cycle.*

Source: Migrant Health: A Primary Care Perspective (with permission)[11]

Refugees move from war, conflict or persecution to find safety in another country (7). People seeking protection from war can be described as refugees, asylum seekers or internally displaced persons depending on their legal status and if they are crossing borders (12). By mid-2020, the United Nations High Commissioner for Refugees (UNHCR) reported that global forced migration had reached 80 million, of which 26.3 million are refugees, 4.2 million are asylum seekers and 30–40 million are children. This is the highest level of displacement to occur since the Second World War (13). In addition, there were 5.5 million registered refugees with the United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA), and 45.7 million internally displaced people due to violence and war, which is the highest number on record since 1998 (13, 14).

9.2. SYRIAN REFUGEES

A total of 13.1 million Syrians are displaced, of which 6.6 million are refugees and 6.4 million internally displaced (15). Syria has had the highest number of people in need of protection since the civil war began in 2011. They have been forced to leave Syria and seek refuge in neighbouring countries or even further away in Europe. Turkey hosts the largest number, with 3.6 million Syrian refugees. Lebanon has more than a million displaced Syrians and Europe has about 1 million, with Europe, Germany and Sweden receiving the highest number of refugees (13, 15-17). Consequently, Syrians have become the biggest refugee group in many European countries, including Norway (18). **Figure 2** shows the number of Syrian refugees by country.

During the violent civil war and the subsequent flight from their home country, Syrian refugees have been frequently exposed to potentially traumatic events, such as life threats, accidents or deaths (19, 20). It is essential for Syrian refugees to obtain security and safety in a new country that also offers them good prospects for the future and a new start in life, especially after all the struggles and challenges of their earlier life (19).

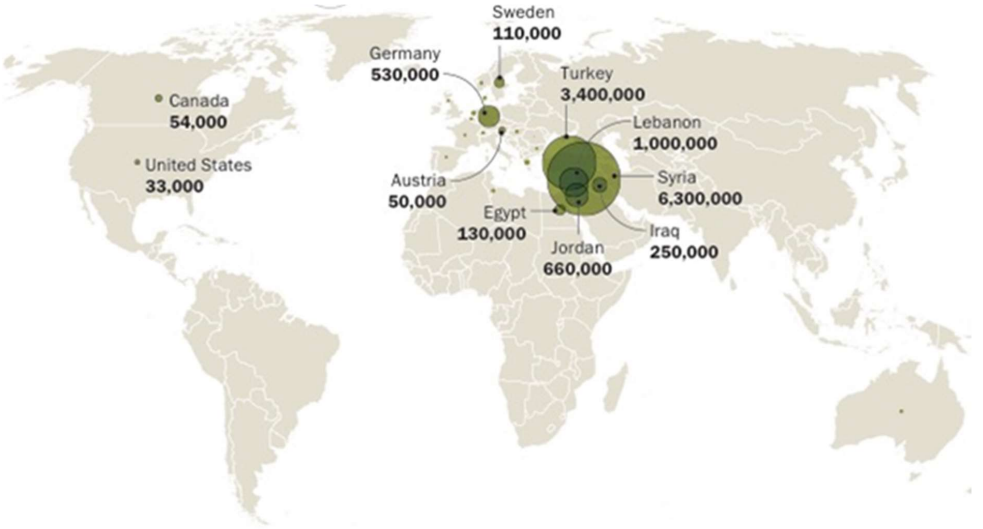

Figure 2: *The spread of Syrian refugees across the world*
Source: Figure from the Pew Research Center. Reprinted with permission[17]

9.3. SYRIAN REFUGEES IN NORWAY

In Norway, 27% of all migrants have a refugee background (21). Due to the war in Syria, a tripling in the number of refugees was observed in Norway (22). More than 31,000 asylum seekers were registered in 2015, and 10,536 of them were of Syrian origin (22). By January 2019, 29,500 Syrians were resident in Norway (21), and Syrian refugees were still the largest registered group of refugees/asylum seekers in Norway in the last three weeks of 2020 (23, 24). More than 87% of the refugees from Syria have stayed in neighbouring countries before arriving to Norway (25).

The UNHCR decides who should be resettled in other countries depending on the resettlement criteria they fall under: legal and physical protection needs, survivors of violence and torture, medical needs, women and girls-at-risk, family reunification, lack of foreseeable alternative durable solutions, and children and adolescents-at-risk. In this setting, a quota refugee is a person who does not live in the reception centres, has resettlement and has agreed to be a refugee (26). The Norwegian authorities (the Norwegian Directorate of Immigration or UDI) determine the goal categories and the

number of quota refugees to be resettled in Norway annually. Each municipality has the sovereign right to determine and decide on the number of refugees that may settle there in any given year (27). Moreover, Norway has its own refugee integration plan, with greater responsibility given to the municipalities to determine whether and how many refugees settle down within the municipality. Since 2019, however, new requirements are in place for municipalities to settle refugees depending on the results of the introduction programme, the local labour market, the municipality's competence and its capacity to ensure the process of refugee integration (27, 28). Although integration in society and the work of integration marked is tightly linked to general health of the refugees, very little is known about the Syrian refugees who come to Norway in terms of their health and there is scarcity of research in this area.

9.4. Migration And Health: Theories

9.4.1. Healthy Migrant Theory

Several hypotheses have been used to explain the health differences between migrants and non-migrants, the 'healthy migrant effect' being one among those. The healthy migrant effect explains the relatively lower morbidity among migrants compared to the general population of the host countries through a selection effect: the healthier and more resourceful persons migrate to another country looking for a new life. This explains why migrants are healthier on arrival and during the first few years in their new home country (11, 29). Although migrants generally show the same spectrum of disease as the majority population, there might be some differences. This is true because migrants don't cross just one border into their neighbouring country; rather they enter different countries depending on developmental status and background (30). Migrants can be exposed to various risks during the travel process such as unhygienic living conditions, abuse and torture in detention camps (10). In addition, migrants undergo chronic repeated stress before, under and after migration that is related to increased stress levels or even to Post-traumatic Stress Disorder (PTSD) (11, 31).

In general, refugees are at high risk of developing health problems due to unfavourable pre-, peri- and post-migration experiences and their vulnerable situation (32). Potential health risk factors can influence migrants' health outcomes. Pre-existing health risk factors or those acquired while travelling may include the geographical origin of the migrant, living conditions at the refugee camp or urban environments, and migrants' personal, physical and psychological conditions (33, 34). In some cases, refugees could be affected by chronic diseases that are rare in the country in which they eventually settle or understand mental health differently.

9.4.2. ALLOSTATIC LOAD AND THE EXHAUSTED MIGRANT

Although the healthy migrant theory is proven across countries and settings, migrants' health seems to deteriorate over time, becoming equal to or poorer than the majority population (11, 29). Allostatic load is the mechanism often used to explain how stress can lead the transition from a 'healthy' to an 'exhausted' migrant. Theoretically, allostatic load explains how when stress factors are constantly activated over time, becoming chronic, the acute stress response in human bodies becomes maladaptive. It explains the long-term effects of chronic stress on the body from continued exposure to frequent stresses (35). Thus, even though migrants on average are in good health when they arrive in the host country, their health status may deteriorate over additional years of stay leading to the 'exhausted migrant' due to various reasons (36). Poor dietary habits and an inactive lifestyle were initially considered to be partly responsible for this deterioration in health (37, 38). This term 'exhausted migrant' explains the excess of impairment in migrants which could be attributed to risky jobs, higher mobility, inadequate training, language problems and the additional stress of adapting to a new situation (38).

However, whether and to what degree the 'healthy migrant effect' or the 'exhausted migrant effect' applies specifically to refugees remains under study.

9.5. Resilience and Sense of Coherence

The salutogenic theory considers health as an ease/disease spectrum, looking for changes in the direction of the health (ease) end (39). Salutogenesis is a valuable way of understanding migrant health promotion and deserves to be used in practice more than it is to date (40). It includes two concepts: resilience and sense of coherence (SOC). Resilience in health refers to how people can cope with and recover from their experiences, including illness, stress, emotional trauma, and social and cultural deprivation (41). A person's SOC helps him or her handle stress, recognize and mobilize external and internal tools, facilitate successful coping by seeking solutions, and overcome conflict in a healthy way. When a person lives an event with a SOC, the world is experienced as comprehensible, manageable and meaningful. Thus, SOC appears to promote well-being, strengthen resilience and encourage a subjective health state.

The migration process may challenge the SOC of an individual and his/her capacity to perceive life. From a salutogenic perspective, this may have a negative impact on the experience of health (42-44). On the other hand, a recent international study indicates that migrant adolescents showed greater resilience than non-migrants, and while migrants encountered more stressful experiences, the effect of trauma on mental health outcomes was greater in non-migrants (45).

9.6. Pain among Refugees

Pain is an unpleasant sensory experience associated with actual or potential tissue damage, and chronic pain is usually defined as pain lasting longer than six months (46). Chronic pain may adversely affect the physical function of the individual as well as their psychological health (47, 48). Several studies have shown people with chronic pain displaying variations in regions of the brain involved in cognitive and emotional pain control (49). This dynamic interplay may explain why anxiety and depression are common among patients with long-term chronic pain, but also why those with cognitive

distortion and psychological distress are at elevated risk of chronic pain and central pain amplification (49, 50).

A systematic review presented the epidemiology of chronic pain in different countries among adult patients. On average, 20% to 25% of a given population presented chronic pain in a region of the body, while chronic generalized pain was present in approximately 10% of the population (51). Chronic pain affects 12% to 25% of people in the United States and 19% of Europeans (52, 53). Pain is a common disorder among refugees. Table 1 shows the prevalence of chronic pain among refugees in different countries and settings showing very different prevalence. Two of the studies (Lebanon 2015 and Turkey 2020) present pain in a region of the body, while the rest present generalized chronic pain. A Danish study shows that traumatized refugees continue to suffer from pain even 10 years after the torture took place (54).

STUDY	TARGET GROUP	PREVALENCE OF CHRONIC PAIN	STUDY SETTING
Thailand 1993 [55]	Cambodian displaced persons	15%-20%	Adults selected from household rosters
Sweden 2001[56]	Adult refugees	73%	War-wounded refugees investigated during hospitalization
Norway 2006 [57]	Adult refugees	76%	Psychiatric outpatient clinic
Denmark 2006 [58]	Adult refugees	83%	Rehabilitation clinic for torture victims
Lebanon 2015 [59]	Syrian refugees	47%	Older refugees from Syria receiving assistance from the Caritas Lebanon Migrant Center or the Palestinian Women's Humanitarian Organization
Norway 2015 [60]	Adult refugee	66%	Psychiatric outpatient clinic
Norway 2019[61]	Syrian refugees	30%	Adult Syrian refugees in Lebanon and Norway (CHART)
Germany 2020 [62]	Adult refugees	31%	Reception for asylum seekers in Leipzig, Germany
Turkey 2020[63]	Syrian refugees	38%	Syrians registered for temporary protection in the Sultanbeyli district of Istanbul, Turkey

Table 1: *Prevalence rates of chronic pain among refugees in different studies conducted between 1993 and 2020*

9.7. MENTAL HEALTH AMONG REFUGEES

Forced migration may have a negative effect on the health of refugees because of conflict and other threats in the country of origin or during flight, as well as acculturation

stress in a new country. Such stressors can lead to mental health problems such as depression, anxiety and/or PTSD (64-66).

Studies among refugees report a broad variety of prevalence rates for depression (3% to 86%), anxiety (5% to 90%) and PTSD (0% to 99%) (67-69). Additionally, trauma-related depression, anxiety and PTSD are particularly prevalent among unaccompanied refugee minors (URMs) (70, 71). Generally, the prevalence rates of mental health disorders among refugees differ widely across studies (68). This could be due to several factors such as refugees' cultural and education backgrounds; differing experiences of integration in the new country; differences in study methodology, type of interviewer, the questionnaires used to assess mental health disorders; and, very importantly, whether refugees are recruited from the whole population or mental health clinics (69, 72, 73).

A systematic review reported that Syrian refugees were 10 times more likely to experience post-traumatic stress and other mental health disorders than the general population, showing wide-ranging prevalence rates for depression (20%-44%), anxiety (19%-32%) and PTSD (23%-83%) (74). Table 2 presents the prevalence rate of mental health disorders among young and adult refugees from Syria.

STUDIES	STUDY POPULATION	DEPRESSION	ANXIETY	PTSD	STUDY SETTING
Thailand 1993[55]	Cambodian displaced persons	55%		15%	Adults selected from household rosters
Belgium 2014 [71]	unaccompanied refugee minors	44%	38%	53%	Resettled refugees in Belgium and Norway
United States 2014 [75]	Syrian refugees	54%	54%		Syrian refugee and internally displaced populations in Syria, Lebanon, Turkey and Jordan
Sweden 2017 [76]	Syrian refugees	40%	32%	30%	Refugees resettled in Sweden
United States 2019 [77]	Syrian refugees	48%	40%	32%	Refugees screened at one-month mandatory primary care health visit
Norway 2020 [34]	Syrian refugees	35%	35%	7%	Resettled refugees in Lebanon and Norway (CHART)
Germany 2020 [78]	Syrian refugees	31%	16%	13%	Refugees have residence permission
Turkey 2020 [65]	Syrian refugees	35%	36%	20%	Refugees selected through the registration system of the district municipality
Germany 2020 [62]	Adult refugees	22%	31%	35%	Reception for asylum seekers in Leipzig, Germany

Table 2: *Prevalence rates of mental health disorders among refugees in different studies conducted between 1993 and 2020*

9.8. COMORBIDITY: PAIN AND MENTAL HEALTH

A recent study shows that regardless of the extent of the traumatic events, pain is one of the most frequently recorded symptoms of patients with mental health disorders (14). Similarly, patients with chronic pain often present symptoms of poor mental health. Further, chronic pain and mental health disorders are mutually maintaining conditions and there are many mechanisms in which both disorders may be involved in the worsening of symptoms and may apply simultaneously (79), i.e. bad mental health will make chronic pain worse, and vice versa, in a mutually disadvantageous relationship. These results suggest that in the cognitive, behavioural and physiological domains, mental health disorders and chronic pain share similar response patterns indicating a complex connection between these two disorders (79, 80).

In an Australian study among adults, the most common mental health disorder associated with chronic pain was severe depression, with 30% to 40% people reporting mental health conditions also receiving treatment for chronic pain (81). A Norwegian study among psychiatric outpatients with a refugee background reported comorbidity between PTSD and chronic pain (60). Denmark, the United Kingdom (UK) and Germany have also reported similar findings (82-84). On the other hand, several studies show that people living with chronic pain often present high rates of anxiety and PTSD (50, 81, 83, 85). The prevalence of PTSD among people with chronic pain ranges from 10% to 50%, while the prevalence of chronic pain among people with PTSD ranges from 20% to 80%, as reported in other comorbidity studies (79, 86).

The trauma experiences among Syrian refugees in Lebanon and Norway have been associated with both chronic pain and depression, anxiety and PTSD (34). There are various comorbidities for traumatized refugees, including mental health symptoms, somatic diseases and chronic pain (8). The high rate of PTSD symptoms, comorbidity and poor physical health was associated with the exposure of Syrian refugees to the war (87).

9.9. Integration and Healthcare for Refugees

Generally, migrants' health receives limited attention (11, 88). However, it is very important for a host country to be responsible for the refugee integration process upon arrival. Good health is usually recognized as a facilitator for successful integration. Ill health, on the other hand, affects one's ability to engage in the education system and the labour market and to participate in society in general, and may therefore put migrants and their children at risk of social exclusion (89). Furthermore, poor integration can lead to deterioration in health. A recent systematic review and meta-analysis of restrictive integration policies has shown an increase in mortality and poor self-rated health among migrants in high-income countries with restrictive policies (90). Several other studies show that poor integration can adversely affect both physical and mental health (91, 92).

Therefore, migrants' ill health is a complex challenge that should be understood and addressed (36).

Everyone, including refugees, has the right to good health. UNHCR's top priority is ensuring that refugees have access to healthcare (93). Refugees should have access to the same or equivalent healthcare as host populations, according to the 1951 Refugee Convention (7). Many European countries provide refugees with universal health coverage and try to ensure equal access to quality health services once refugees are established in the host country (93, 94). Access is a significant principle in health services research that refers to the use of the healthcare system or factors affecting the use of the healthcare system. Access as a general concept summarizes a set of more specific dimensions describing the fit between the patient and the healthcare system The specific dimensions of access to care are: availability, accessibility, accommodation, affordability and acceptability (95).

In Norway, all migrants have the same legal right to healthcare as the Norwegian people, with the exception of illegal migrants. Municipalities are responsible for delivering healthcare services that are appropriate for early detection and follow-up to somatic and mental health issues (96). In Norway, people with chronic pain and/or mental health symptoms are usually monitored through follow-ups with primary healthcare services including general practitioners and physiotherapists or psychologists (27) . However, there is limited availability of care and follow-up in many regions, especially when an interpreter is needed.

Refugees could face many general challenges in their new country including communications difficulties due to linguistic and cultural differences, acculturation, intergenerational conflict and aspects of acceptance by the host culture affecting employment, social status and integration (97). Such risk factors can lead to complex difficulties when refugees try to access healthcare systems in the host country (2). An Australian study among refugees found several barriers to accessing healthcare, including language barriers, not knowing where to seek help, and poor understanding

and insufficient knowledge of how to access health services (98). A literature review found that migrants might face major language and health literacy problems, which are compounded by cultural and economic obstacles to getting accurate health details (99).

The use of interpreter services in healthcare settings represents one of the main challenges facing migrants in their new country. A Norwegian study among Polish migrants showed that access to interpreters was restricted or refused due to the lack of integration of interpretation services in organizational routines and an overestimation of the patient's language abilities. Using friends, family or bilingual workers instead of licensed interpreters also affected the accuracy of the interpretation in many ways (100).

A systematic review shows a range of difficulties and facilitators that have been recognized for health professionals providing primary healthcare for refugees and asylum seekers in high-income countries. These include trust, communication, cultural understanding, health and social conditions, time, training and guidance, professional support, connecting with other services, organization, resources, and capacity (101) **(figure 3)**.

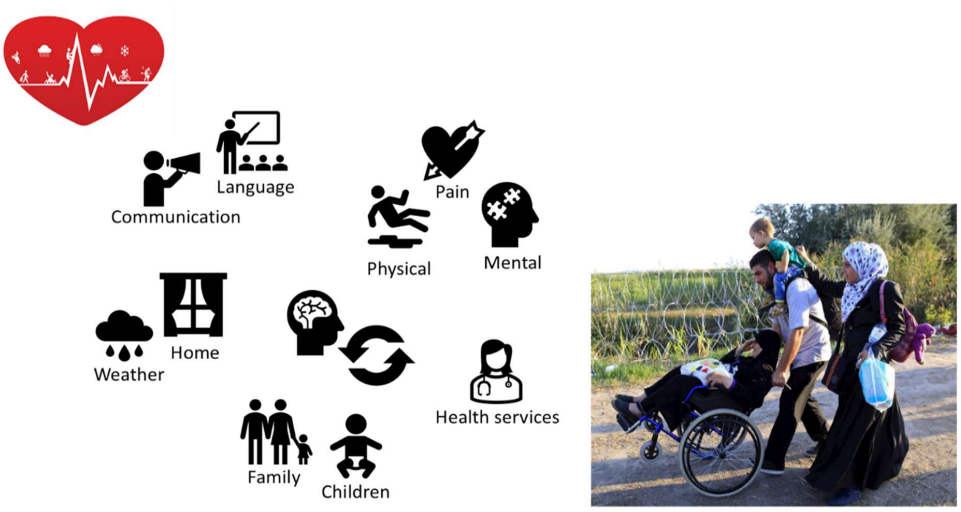

Figure 3: *Challenges facing refugees in a new country.*
Source: Photo: August 2015. Bernadette Szabo, Reuters, NTB Scanpix. Reprinted with permission.

Several studies among refugees and asylum seekers in Europe showed that these refugees often have high mental health needs (102, 103). However, studies also indicate the underutilization of mental health services in the host country because of certain specific challenges. Language, lack of awareness, fear of stigmatization from their own culture, and a negative representation of psychiatry are all described as major barriers to accessing mental healthcare. A recent study among asylum seekers in Switzerland discovered that 66% of asylum seekers risked being stigmatized by their families because they sought mental health treatment (103). Tradition and culture can also influence the understanding and management of chronic pain and mental health (104). Therefore, refugees should be offered suitable and culturally acceptable forms of healthcare in the host country (105). By promoting social inclusion, designing outreach programmes, organizing culturally sensitive healthcare, sharing information about entitlements and services, and training healthcare professionals to work with these groups, one can achieve good practices for mental healthcare and chronic pain treatment (2).

9.10. Culturally Targeted Interventions

Culture refers to a particular community or group of people who share characteristics and self-awareness, including, among others, language, social behaviours, music, arts, and religion. Culture is an important part of health and promotion, and current health systems need to be culturally sensitive in an increasingly diverse society. Therefore, there is growing recognition that some interventions must be culturally tailored to meet the needs of specific population groups in order to be effective. However, culture is a fluent concept with regard to the individual and the system, and both persons and interventions can culturally adapt to any situation. On the one hand, a person's cultural adaptation is defined as the process and time taken by a person to integrate into a new culture (106, 107). On the other hand, the goal of cultural adaptation of an intervention is to increase its efficacy by grounding it in the participants' lived experience (108, 109).

For the individual, there are four stages in the theory of cultural adaptation. The first is the honeymoon stage, characterized by a deep sense of satisfaction, which normally lasts from the time of arrival until the first few months in the new country. The second stage is the crisis period or culture shock, a feeling of dissatisfaction that appears three to four months after arrival. The third stage is the recovery or adjustment stage in which there is a feeling of being more familiar with people and the new culture. The last stage is the feeling of acceptance and adaptation (108).

In the field of public migrant health, targeting treatments in a culturally appropriate way is a widely used strategy that focuses on the creation of specialized health interventions for a particular group of people (11, 110). A previous qualitative study among South Asian migrant populations showed the key factors to successfully culturally adapting an intervention: 'approaching the community in the right way', 'the intervention as a space for social relations', 'support from public authorities' and 'being reflexive and flexible'. The challenges identified were 'struggling with time' and 'overemphasizing cultural differences' (105)

Maintaining harmony between people and their environment is essential in Arab society (111). In non-clinical settings, interventions that are culturally appropriate are as important as the type of mental health treatment received from a professional clinician (112).

Interventions using cultural influence show great potential to minimize healthcare inequalities (113). A common approach to enhancing the quality of healthcare for culturally and ethnically diverse communities is to discuss the cultural competence of the health staff to deliver health education and health information to these communities to improve their access to health services (98, 105, 114).

The resettlement of some refugees in new countries may occur without reliable and appropriate information provided to them about the new country. When refugees move to a new country, most frequently not selected by the refugee, under uncertain conditions and with uncertain futures, they must adjust to a new place and a new language. This in

turn can create many challenges for the refugees in the new country, in addition to the dramatic changes that they may face in their day-to-day life upon migrating and living in a new environment (28). Hence, in order to adapt interventions in an appropriate way, it is also necessary to have a basic understanding of the 'refugee process' to identify the difficulties that refugees may encounter when re-establishing a home and identity in a new country, a significant challenge upon migration (115).

9.11. Individual Therapy versus Group Therapy

Individual therapy is described as a therapeutic phase where one therapist treats one individual on a one-on-one basis. Group therapy is when a small group of clients are treated together with at least one therapist (116). There are advantages and disadvantages to both types of therapy. Individual therapy offers several advantages:

- patient confidentiality is easily maintained in this type of therapy;
- the one-on-one attention from the therapist is very focused and patients can also concentrate more on the therapeutic intervention;
- the relationship between patient and therapist is very strong and allows for the development of communication skills in patients who need help with these skills;
- patients can arrange their therapy sessions quickly if needed.

On the other hand, in terms of the disadvantages, individual therapy is usually more costly than group therapy, and the participant may struggle with being the centre of attention in a one-to-one meeting. (116, 117).

The advantages of group therapy are:

- it is usually less expensive than individual therapy;
- patients can share similar problems and challenges with other individuals and receive support from each other, allowing the integration of several points of view;

- it helps participants develop communication and socialization skills and teaches them to express their complaints and receive feedback from others;
- it might also help develop self-awareness by listening to others who have the same problems and share own experiences;
- it can provide a safety net to individuals who may hesitate to discuss their innermost thoughts and feelings;
- individuals in group therapy can model the successful behaviour of other individuals who have had similar experiences.

Conversely, in group therapy, the focus and attention is not on one person. For some people, this type of therapy may be inappropriate as they would be better suited to one-one-one therapy. The level of confidentiality in group therapy is far less. Groups tend to meet according to a fixed schedule. Lastly, groups can allow people who are unmotivated to hide their problems and avoid accountability (116, 117).

A recent systematic review and meta-analysis showed no clinically significant differences in outcomes obtained by group and individual physiotherapy. However, the review pointed out that group interventions should be considered due to their comparable efficacy and potentially lower healthcare costs (118).

Refugees who often lack social interaction with peers upon arrival in the new host country may prefer group dynamics (8, 119). However, some might feel threatened or might not feel comfortable sharing their experiences with other persons of the same origin, but with whom they do not share a political or social background.

9.12. Group Therapy for Chronic Pain Among Refugees

Treating chronic pain often includes helping patients improve their daily function and quality of life. Generally, the treatment for chronic pain involves medication, physical therapy, exercise, acupuncture, relaxation techniques and/or psychological counselling (120). In the last 30 years, physiotherapy professionals in the Scandinavian countries have developed the Basic Body Awareness Therapy (BBAT) (121). BBAT consists of

breathing exercises, massage, and movement. It was developed as a combination of Western and Eastern traditions of personal development (122, 123). BBAT is also one of the most used forms of physical activity in the care of traumatized refugees that has been tested to improve mental health symptoms (124). Psychomotor physiotherapy is a branch of BBAT that focuses on the relationship between body and mind. It was established in Norway in the late 1940s to enhance and normalize muscular control through body awareness strategies and enable the patient to become conscious of how the mind and body interact (125).

There are many interventions that target the acceptance of pain, which differ in their therapeutic implementation and approach and daily practice such as meditation, Cognitive-Behavioural Therapy (CBT), Mindfulness-Based Stress Reduction (MBSR) and Acceptance and Commitment Therapy (ACT). Meta-analytic studies indicate a small effect of these interventions on pain (126-128).

9.13. Group Therapy for Mental Health Among Refugees

A previous systematic review among adult refugees indicates that culturally adapted Eye Movement Desensitization and Reprocessing (EMDR), CBT, Narrative Exposure Therapy (NET), Traditional Chinese Medicine (TCM), Emotional Freedom Techniques (EFT) and Mindfulness-Based Trauma Recovery for Refugees (MBTR-R) all had positive outcomes on both pain severity and/or mental health symptoms (129-133).

The World Health Organization has developed a psychosocial intervention that has been implemented for Syrian refugees with mental health disorders and related somatic symptoms called Problem Management Plus (PM+) (134). Teaching Recovery Techniques (TRT) is a group intervention based on CBT concepts that has helped reduce the symptoms of PTSD among traumatized young refugees in Europe and Palestine (9, 135-137). TRT has not yet been evaluated for adults but has been used at the municipality of Bergen for some years. Therefore, it was chosen for assessment as one of the very few self-help group interventions targeting refugees with both established diagnosis and symptoms and based on clinical experience.

9.14. Summary and Rationale for the Present Study

Syrian refugees are a growing group in Europe and present high prevalence of both pain and mental health disorders. A previous scope review found a research gap in mental health services and practices provided to migrants in primary care in high-income countries (138). Until now, there is also little evidence evaluating the specific interventions that address the demand for the treatment of traumatized refugees with mental health symptoms and/or chronic pain (8, 131). More specifically, there is a lack of randomized controlled interventions in this field—the gold standard to study the effect of any intervention—in addition to other methodological shortcomings in the few existing studies (139, 140).

The lack of evidence of effective and feasible treatment options for adult refugees suffering from mental health problems and chronic pain can threaten the availability and quality of the health services provided, especially when the situation is combined with special needs (e.g. proficiency in the host country's language, limited resources from the municipalities). It is, therefore, essential to establish and assess strategies and procedures that effectively address the chronic pain and post-traumatic symptoms that adult refugees suffer. This PhD study aims to address some of these issues.

10. OBJECTIVES

The main objective of this thesis is to evaluate the effect of two group interventions in reducing chronic pain and/or post-traumatic symptoms among adult Syrian refugees. To this aim, we conducted a 2x2 armed randomized controlled trial (RCT) in order to answer the following questions:

Research question 1: What is the effect of a group-based physiotherapy intervention on physical and mental health among refugees with pain disorders?

Our hypothesis in this research question is that group physiotherapy treatment should reduce pain levels among Syrian refugees who resettled in Norway, and also improve their mental health. Thus, our primary aim is to evaluate the effect of Physiotherapy Activity and Awareness Intervention (PAAI) on reducing the degree of pain and secondarily in improving general mental health. Additionally, we will also assess participants' experiences with PAAI.

Research question 2: What is the effect of a self-help group intervention using Teaching Recovery Techniques (TRT) on the mental and physical health of refugees with mental health symptoms?

In our second research question, we hypothesize that self-help groups using TRT would improve mental health and secondarily reduce pain levels. Our aim therefore is to assess the effect of TRT on improving mental health and secondarily in reducing chronic pain among the Syrian refugees.

The study protocol is described in Paper I. Papers II and III present the RCTs that assess the effect of the two group interventions among adults' Syrian refugees. Table 3 summarizes the objectives and methodology of the papers that comprise this study.

SPECIFIC OBJECTIVES	DESIGN	PARTICIPANTS	DATA COLLECTION	ANALYSIS
I. To describe in detail 2×2-armed randomized controlled trials evaluating PAAI and TRT	Protocol and planning of RCT	Not applicable	Not applicable	Not applicable
II. To evaluate the effect of PAAI on reducing pain disorders and improving mental health symptoms, and also on participants' experiences with the intervention	Randomized waitlist-controlled trial, Semi-structured interview	N=101 Syrian refugees with pain symptoms compared to mental health symptoms, n=50 intervention group and n= 51 control group N for interviews, n=17	August 2018 to December 2019	Intention-to-treat principle (ITT), linear mixed model, intraclass correlation coefficients, longitudinal analyses, thematic analysis
III. To assess the effect of a self- help group intervention using TRT to improve mental health symptoms and to reduce pain disorders	2 × 2-armed randomized waitlist-controlled trials,	N= 76 Syrian refugees with mental health symptoms compared to pain disorders, n=38 intervention group, and n=38 control group N for interviews, n=21	August 2018 to December 2019	Intention-to-treat principle (ITT), linear mixed model, intraclass correlation coefficients, longitudinal analyses

Table 3: *Summary of the objectives and methodology of the studies comprising the thesis*

11. Design, Materials and Methods

The study protocol was written according to the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) recommendations for intervention trials. Paper I is a study protocol for the RCTs of two group interventions among adult Syrian refugees with chronic pain and mental health symptoms. More details on Paper I can be found in appendix, but a summary description is given below.

11.1. Study Design

An RCT design was chosen to evaluate the effect of two different group interventions on treating pain and mental health symptoms. Our study is designed as a 2x2 armed randomized waiting list-controlled study comparing each intervention to a control arm. The interventions were conducted in parallel, with PAAI lasting eight weeks and TRT lasting six weeks. After the intervention was completed in the intervention arm, the control arm was given the same intervention. For the rest of the thesis, we call the groups intervention and control. The same model was used in both the PAAI and the TRT interventions. This design allows the interventions to be evaluated and has additional advantages in the implementation of the RCT in two arms.

11.2. Protocol and Registration

The trial NCT03951909 was retrospectively registered on 19 February 2019 on ClinicalTrials.gov. The trial was submitted while recruitment was ongoing. No significant changes two either analyses or outcomes were made during recruitment.

11.3. Ethical Considerations

The study was accepted by the Regional Ethics Committee on 20 June 2018 (REK 2018/603). Written informed consent was obtained from every participant in their own language, one at the baseline and the other at the beginning of the interventions (Supplementary 1&2).

Since it would be unethical to refuse participants access to treatment when diagnosed with pain disorders and/or mental health symptoms, we decided on delayed intervention. Accordingly, we chose an immediate versus delayed intervention study design for both interventions. Using one intervention as a control for the other would not be sufficient. This delayed intervention can also result in less loss to follow-up among participants in the control group because they know they will receive the intervention eventually (141). However, the delayed intervention design, although ethically appropriate, can make it difficult to determine potentially delayed effects that could occur at a later stage that were not present immediately after the intervention. A regular meeting was held by the research team and the municipality of Bergen to ensure adherence to the protocol and ethical standards, and to follow the overall progress of the interventions.

11.4. STUDY SETTING

In Norway, people with chronic pain are usually monitored through follow-ups with primary healthcare providers such as general practitioners and physiotherapists. Refugees have the same entitlements and access to healthcare as Norwegians. However, many regions, including Bergen, have limited treatment and follow-up options, particularly when an interpreter is required or with chronic patients. Similarly, people with mental health problems are usually monitored through follow-ups with primary healthcare and/or secondary healthcare professionals such as psychiatrists and psychologists (generally requiring a referral). However, many regions, including Bergen, have limited access to psychological follow-up, and specific cultural competence is scarce. Consulting private physiotherapists and psychologists is always an option, but private treatment is expensive.

11.5. PARTICIPANTS

We invited adult Syrian refugees (aged ≥ 16 years) who lived in Bergen and neighbouring municipalities to participate in the study. Recruitment was organized in

three waves, followed by three rounds of interventions. **Figure 4** illustrates the timeline of the implementation of the interventions.

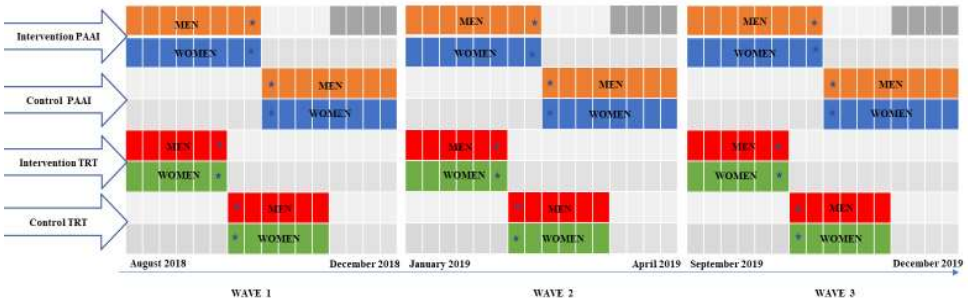

Figure 4: *Timeline of the interventions*

Note: The intervention and control groups of PAAI and TRT for men and women started between August 2018 and December 2019. Each box represents one week.

** Outcome assessment at the last treatment session in the intervention group and at the first session for the control group.*

11.6. Inclusion and Exclusion Criteria

To be enrolled in one of the two interventions, participants had to report either chronic pain and/or mental health symptoms. Participants were eligible for PAAI if they had physical pain which lasted more than six months and if they scored 3 or higher on one of the two pain severity items measuring average and current pain ranging from 0 to 10 on the Brief Pain Inventory (BPI) short questionnaire. Participants were eligible for TRT if they answered yes to the question 'Have you experienced any of these or some other terrifying event(s)?' and scored over 24 on the Impact of Event Scale-Revised (IES-R) that had a total score from 0 to 88. Any participant who scored 25 or more on the General Health Questionnaire-12 (GHQ-12) was assessed by the team psychologist to ensure that he or she could benefit from group therapy or be referred for individual therapy. Since we expected high comorbidity between pain and mental health complaints, participants were assigned either to the PAAI or the TRT according to their symptoms. Those who had both pain disorder and mental health symptoms were invited to the group intervention where the percentage in IES-R or BPI was highest.

Our exclusion criteria included participants who (a) had a health problem in need of close medical supervision (e.g. diabetes with complications or cancer that was being treated) or (b) were unable to attend the group intervention because they lived far away from the location of the group meetings. A high score on the mental health questions suggests that a participant has a significant mental disorder (GHQ-12 score of 25 or more) and such persons were, as explained above, evaluated by psychologists for individualized counselling. There were 25 participants who scored more than 25 in the GHQ-12 and were accordingly assessed by the psychologist, but only one of them was excluded for this reason. No other patients were excluded from the study.

11.7. RECRUITMENT

We recruited adult Syrian refugees (16 years and above) from different backgrounds and walks of life living in Bergen and the surrounding municipalities:

(i) a group of approximately 30 students from educational programmes;

(ii) patients from primary and secondary healthcare facilities, particularly those from areas with a large number of migrants;

(iii) individuals from places where refugees frequently gather, such as Middle Eastern and Asian grocery stores and barber shops.

We recruited participants who were eligible to participate. **Figure 5** shows the CONSORT flow chart for both interventions. Two posters, one in Arabic and one in Norwegian, were delivered to all the places mentioned above, and were placed on the doors and entrances of schools, shops and waiting rooms of practices of medical clinics for Syrian people to read and contact the author directly. The posters carried the following message: 'Do you have persistent pain in your body (for example, in the neck, back and joints)? Do you often feel sad, suffer from anxiety, or feel unhappy? The University of Bergen, together with the Centre for Migration Health in Bergen municipality, offers you free treatment from August' (Supplementary 3). All

participants were asked to contact the first author at any point during the study for more details and future inclusion and were subsequently informed about the study in Arabic by the first author who speaks both Arabic and Norwegian.

We sent a letter in Norwegian to all the general practitioners, physiotherapists, and psychologists in the city centre, Nesttun and Årstad areas of Bergen inviting Syrian patients with chronic pain and/or mental health symptoms to contact the first author (Supplementary 4). All Syrian participants who went to school received an SMS (Supplementary 5) in Arabic from the teachers after we sent the letter to the director of the school (Supplementary 6). The letter invited all Syrians to a first meeting with the first author to get information on this study. Those who agreed to participate filled out the baseline questionnaire (Q0) (Additional File 1). This questionnaire was used to classify participants who met the inclusion criteria for pain and/or mental health symptoms.

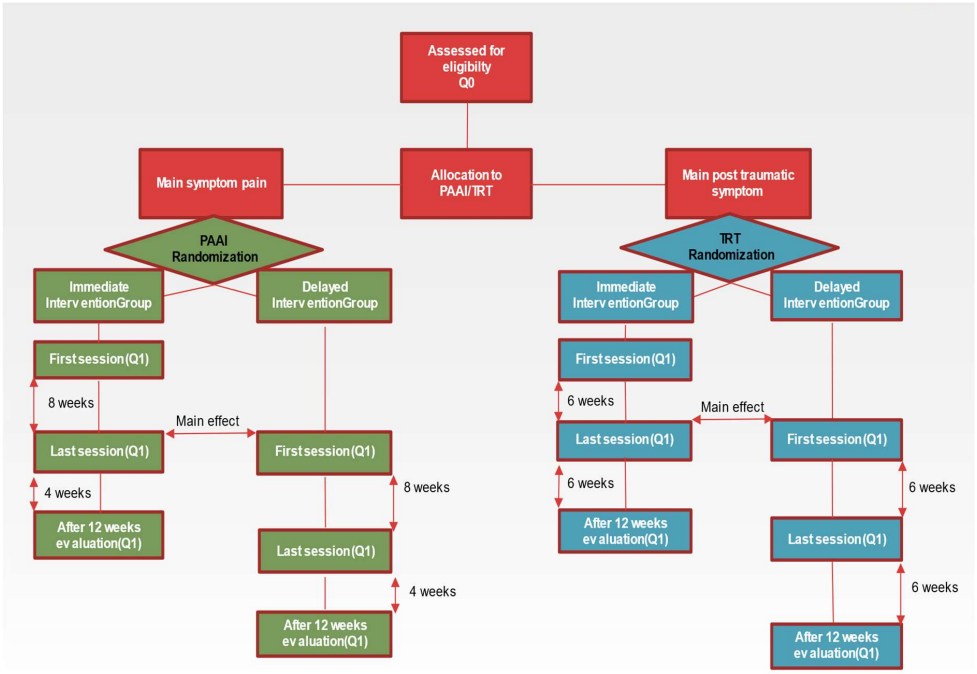

Figure 5: *CONSORT flow chart*

Note: PAAI: Physiotherapy Activity and Awareness Intervention, Q0: Questionnaire 0, Q1: Questionnaire 1, TRT: Teaching Recovery Techniques

11.8. Development and Implementation of the Interventions

The CHART study, in close collaboration with the Centre for Migration and Health and the Centre for Crisis Intervention in Bergen, developed two interventions: one for participants with chronic pain as their main complaint and another for those with predominantly mental health symptoms. This is explained in the next section.

A consulting group of eight Syrian refugees (four men and four women), not included in the study, from different backgrounds and holding different positions in society, was formed in May-June 2018. Both meetings, one for the male group at the Department of Global Public Health and Primary Care and the other for the female group at Nygaard School, were organized in Bergen. The two meetings were conducted in Arabic by the first author. The ages of the group members ranged from 19 to 63 years, covering a

range of educational levels, from primary school to university/college. For the male consulting group, the snowball sampling method was used by contacting one of the Syrians who works as a barber, who then contacted other Syrians. The female group was contacted from the school where refugees learn Norwegian. These two separate groups were asked for advice on issues like the necessity of splitting the groups by age or sex; the frequency of the interventions; the most convenient time of the day and week for the interventions; the importance and organization of time for socializing; the necessity of reminders (SMS messages) prior to each session; appropriate clothing; preferences for an interpreter, etc. We tried to follow their advice as best we could when implementing the interventions (142).

All sessions were conducted in Norwegian with an Arabic interpreter. The words and phrases that the therapists used for instruction were shared with the interpreters beforehand, since there was a possibility of some variation in Arabic depending on the country the interpreters were from. As a result, all the interpreters were well prepared. As suggested by the consulting groups, we tried to ensure that the therapist and the interpreter were the same gender as the group. Each participant was contacted three times before each session by the author: one week before the session, one day before the session and on the day of the session. This was in addition to the SMS message that was sent twice before each session.

11.9. The Physiotherapy Activity and Awareness Intervention (PAAI)

The Centre for Migration Health at the municipality of Bergen developed a group PAAI based on previous clinical experience treating groups of refugees. PAAI is influenced by principles found in psychomotor physiotherapy and BBAT, where the body and consciousness gain increased awareness in interacting with itself and its surroundings (143). PAAI was conducted by the two physiotherapists (one male, one female) involved in this project. Each session consisted of the same key elements and lasted for an hour, once a week for eight weeks (142). Participants were instructed to pay attention to their

own pain and limitations in range of motion and were actively asked to report any injury during the session to the physiotherapists. As described in the protocol, the therapists kept to the pre-decided plan. In every session, the interpreter's Arabic dialect was not generally Syrian, but there were no signs of misunderstanding.

The intervention consisted of eight sessions. The following seven exercises were performed in each session:

I: Start with mindfulness exercises and welcome ball game as an introduction to the session. This was done to encourage participants to communicate with the attendants and concentrate on the task ahead. An example of the mindfulness exercise is the seated body scan. In terms of posture and postural power, sitting is less demanding than standing. Sitting is a more protected position for those who have suffered trauma since the muscles are flexed to an almost foetal position, and the person might feel better sitting than standing. Furthermore, when sitting back, the base of support is larger than when standing. We also did a short round of introductions to build relationships between participants using a soft ball which was thrown to each member who then introduced themselves. Once the introductions were complete, the ball was returned to the physiotherapist. The idea behind this exercise was to get the participants to 'forget themselves' and to also explain how an activity could remove the focus from life's daily struggles.

II: Seated mobility exercises. This involved mobility exercises for the largest joints of the body: foot, knee, hip, back, arm, elbow, wrist, fingers, neck, face, and jaw. The movements of the physiotherapist were copied by the participants, which allowed them to monitor the movement's range of motion, as well as the amount of force they wanted to use. The physiotherapist's speed and tone of voice allowed the participants to interpret their own body. A balance cushion on a chair was used for mobility exercises for the hip and pelvis. The objective was to gently loosen tension in the stomach, hip and pelvis by allowing the diaphragm to expand downwards and the hypogastric region to breathe.

III: Lying down and relaxing. It takes a certain sense of security to find a safe and comfortable space when lying down, and to gradually let the body relax. During this phase of the programme, the participants may also sit. The physiotherapist instructs the participants on how to be conscious of various parts of their body and on how to breathe.

IV: Standing proprioceptive exercises. This exercise increases self-awareness of the body's muscle tension with weight shifting from side to side, adjusting the body's point of gravity to allow the participant to notice changes in their own body's muscle tension and breathing pattern.

V. Active movements stimulating balance. Here, the active movements stimulate balance, coordination, respiration, swaying of the arms, bending of the legs, and mixing numerous patterns of movement.

VI. Coordination and breathing. This involves enhancing the respiratory system function to breath well. At the same time, improve coordination in the context of specific movements to select the right muscle at the right time.

VII. Grounding and a short closing round. Everybody stands in a circle focusing on the contact between the floor and the sole of the foot. In the closing round, we all sat in a circle and everyone got a chance to comment briefly on the day's session.

Every session lasted an hour with 10–12 persons invited into each group. At the beginning of each session, participants were encouraged to push themselves as much as possible for that one hour of therapy.

11.10. THE TEACHING RECOVERY TECHNIQUES (TRT) INTERVENTION

The Children and War Foundation establishes and disseminates effective psychological procedures to support vast numbers of traumatized children (135). TRT is a self-help group intervention previously designed by the Children and War Foundation in Norway for children aged 8-18 years. It is based on trauma-focused cognitive behavioural therapy (TF-CBT). For young people, TRT is scheduled for five sessions and two

additional ones for their caregivers, where each session lasts between 90 and 120 minutes (70). Although TRT is currently being adapted and tested for use among adults, this was not so when the CHART study was designed and implemented (135, 144).

The Centre for Crisis Psychology trained the CHART team, the healthcare practitioners at Bergen municipality and collaborating interpreters on the TRT manual. In this study, the TRT manual was modified for adults and designed in a step-by-step practical way to develop skills that would help in coping with the psychological after-effects of traumatic events. Each TRT session was led by two members of the team who had previous experience working with refugees. Six weekly TRT sessions were delivered; each session lasted approximately two and a half hours with up to 10 participants.

The sessions focused on intrusive thoughts and feelings, arousal and avoidance in that order.

Session I: The objective of the first session was to establish good group dynamics, explain the content and intention of the course and the reactions to stress and trauma, including traumatic experiences, reactions and reminders. The exercise aimed to establish a safe place.

Session II (Intrusion): This involved participants describing flashbacks/intrusive memories and practicing different techniques to handle/gain a sense of control over intrusive memories.

Session III (Arousal): This involved going through the physical expressions of arousal/stress. The exercises aimed to physically reduce arousal.

Session IV (Arousal): This session used cognitive and behavioural techniques to explain the connection between thoughts and arousal, the techniques to limit worrying, the principles to improve sleep, and the tools to deal with repeated nightmares related to trauma. It also involved planning daytime activities to avoid excessive brooding/worrying.

Session V (Avoidance/exposure): This session explained trigger avoidance and the principles of gradual exposure by creating lists of triggers and anxiety hierarchies, and a personal plan to practice exposure to an external trigger.

Session VI (Avoidance/exposure): This session explains the principles for processing a traumatic experience/memory by drawing, writing or talking about it. Participants had to practice by drawing, summarize the content of the course, celebrate victories and look ahead.

To prevent secondary exposure and trauma during group meetings, participants did not need to share or relive painful memories/experiences/examples from their own life. Instead, participants were assigned tasks that were implemented as homework.

11.11. Potential Harms

Through the interventions, we became aware that there was a possible risk of worsening pain or mental symptoms, and the group leaders were therefore qualified to recognize and treat or refer patients who showed worsening symptoms during the meetings. If these symptoms were detected in one participant, individual treatment was recommended based on advice from involved clinicians and with the help of an interpreter. After each session, the interpreter stayed for 30 minutes, for questions, debriefing and coping with what happened that day in the group interventions. This was useful both for the safety of the participants and the interpreters, who often had refugee background themselves which could be influenced by the group's events. Regarding post-trial care, there were no provisions other than those provided by the regular health system. No harm was detected during the interventions.

11.12. Allocation and Blinding

The team statistician created a random allocation sequence using the ralloc command in Stata 15. A block randomization procedure was performed with block sizes ranging between 4, 6 and 8 and a 1:1 allocation ratio. Separate randomization sequences were

generated for PAAI and TRT. There was no access to the randomization list for the individual who recruited participants and assigned participation numbers. The first author recruited and assessed outcomes. During the active intervention level, it was not possible to blind the participants or the instructors in this study.

11.13. Sample Size Calculation

Based on previous findings by our research group among 150 refugees from Syria in Lebanon (142), we assumed a mean of 6.0 and standard deviation (SD) of 3.8 in the BPI pain intensity scale (range 0–10), and a mean of 35.6 points and SD of 15.5 on the IES-R scale (range 0–80) at baseline and used an independent sample t test with 80% power and a significance level of 5% to estimate necessary sample size in each of the two RCTs. We considered a 3-point difference on the BPI scale for the PAAI RCT and 13.1-point difference (0.75 SD) on the IES-R scale for the TRT RCT as clinically significant effect sizes.

For the PAAI RCT, a minimum size of 27 participants was needed in each intervention and control arm based on these calculations. Assuming 25% attrition, it was necessary to recruit a total of 68 participants (34 participants in each of the study arms). Since the groups had a maximum of 10 participants, we needed 3–4 intervention groups and 3–4 control groups for the PAAI. Similarly, for the TRT RCT, we needed a total of 78 assuming 30% dropout, giving us 39 participants per study arm. Therefore, we needed 3–4 intervention groups and the same number of control groups.

11.14. Evaluation and Measurements

All measurements to assess the interventions were collected using two self-completed questionnaires in Arabic (145, 146) under the guidance of a bilingual fieldworker. The same questionnaires were used for both interventions, TRT and PAAI. The more detailed baseline questionnaire (Q0) was used to identify participants. A follow-up questionnaire (Q1) was used at the first and last sessions of the treatments and 12 weeks after the first session (Additional file 2). Q0 and Q1 had three parts: socio-economic and

migration-related information (more extensive in Q0), well-being and sense of coherence (SOC), and health status and health habits. The questionnaires contained instruments that had been translated and validated in Arabic: the 5-item World Health Organization Well-being Index (WHO-5) and the 13-item Sense of Coherence Scale (SOC-13) (147, 148). For the evaluation of physical and mental health in the third part of Q0 and Q1, health-related risk factors and use of non-prescribed medication, questions from The Nord-Trøndelag Health Study (HUNT 3) were used (149). For the assessment of pain, the Brief Pain Inventory-Short Form (BPI-SF) was used. BPI-SF contains four items on pain intensity to describe the pain at its worst, least, average and 'right now' levels (150). The IES-R 22 was used to measure human distress caused by traumatic events (151). The GHQ-12 is a test developed for the general population that was used to assess minor psychiatric symptoms and conditions (152). Written informed consent was obtained from all the participants.

In addition to quantitative measurements, a systematic qualitative observation following a pre-structured scheme (Supplementary 7) was performed to take notes on when and how the interventions were implemented and carried out (one hour for PAAI sessions and two and a half hours for TRT sessions). The first author observed each group at least twice, taking thorough notes to determine whether the intervention met the initial plan and to track behaviour, activity and dynamics of the groups. In addition, short semi-structured interviews among 38 participants, 17 from PAAI and 21 from TRT, including those who completed the intervention and those who dropped out, were conducted (Supplementary 8). Part of this information, however, has not been used in this thesis. The questions used (Additional files 3 and 4) were adapted to those used in Sweden by Sarkadi *et al.* (70) in their assessment of group intervention for unaccompanied refugee minors with PTSD symptoms.

The study protocol was written according to the SPIRIT recommendations. **Figure 6** shows the schedule of enrolment, interventions and assessments. This scheme was repeated three times in order to enrol the number of participants we needed.

		STUDY PERIOD								
	Enrolment	Allocation		Post-allocation						Close-out
TIMEPOINT	*-t1*	*0*	*T1 (1st week)*	*T6 (6th week)*	*TD1 (7th week)*	*T8 (8th week)*	*TD1 (9th week)*	*TD6 (12th week)*	*TD8 (16th week)*	*tx*
ENROLMENT:										
Invitation to persons with pain symptoms and posttraumatic symptoms	X									
Filling out Q0	X									
Allocation PAAI		X								
Allocation TRT		X								
INTERVENTIONS:										
Immediate Intervention TRT			X	X						After 12 weeks
Immediate Intervention PAAI			X			X				After 12 weeks
Delayed Intervention TRT					X			X		After 12 weeks
Delayed Intervention PAAI							X		X	After 12 weeks
ASSESSMENTS:		Q0	Q1for TRT& PAAI	Q1 for TRT	Q1 for TRT	Q1 for PAAI	Q1 for PAAI	Q1 for TRT	Q1 for PAAI	Q1

Figure 6: *Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) schedule of enrolment, interventions and assessments*

Note: PAAI: Physiotherapy Activity and Awareness Intervention, Q0: Questionnaire 0, Q1: Questionnaire 1, TD: delayed intervention (same intervention at a later time point), TRT: Teaching Recovery Techniques.

11.15. OUTCOMES

The two main outcome measures were: (a) pain assessed by the pain intensity domain of BPI and calculated as the mean of the four items (ranging from 1–10) and (b) mental health symptoms measured by IES-R 22 and calculated as the sum of 22 items (ranging from 0–88). As a secondary outcome, general mental health was assessed by the GHQ-12, with a range from 0 to 36. Both effects were assessed in the intervention group right after the intervention was over and after 12 weeks, and in the control group right before the start of the intervention.

11.16. STATISTICAL METHODS

For the two groups within each of the two trial arms (PAAI and TRT), the baseline characteristics were described separately, with medians and interquartile ranges for continuous variables and with counts and percentages for categorical variables. All tests were two-sided and 5% was used as the level of significance.

When estimating the effect of the interventions on the outcomes, the data set was organized as longitudinal data in long format with two observations per individual. The first measurement was outcome measures at Q0, and the second measurement was outcome measures at the last treatment session in the intervention group and the measurement at the first session for the control group. Since the delayed intervention in the control group started one week after the last treatment session in the intervention group, the distance between the first and second measurement was one week longer in the control group. The effect of the intervention on the primary and secondary outcomes was assessed using linear mixed models with random intercept for individuals and the continuous outcomes as dependent variables.

An example of the model set-up for the BPI outcome is shown in formula 1 below:

$$BPI=\beta_0+\beta_1\cdot TIME+\beta_2\cdot TIME\cdot GROUP+b_{0i}+\varepsilon \quad (1)$$

TIME is a binary variable (0/1) with Q0 (time of randomization) as the reference, GROUP is a binary group allocation variable with the control group as the reference and b0i is the random intercept for each individual i. The intervention effect was estimated as the interaction effect between GROUP and TIME. By omitting the main effect of group from the model we achieved an adjustment for baseline differences in the outcome (153). The same model set-up was used for both primary and secondary outcomes in both trial arms (PAAI and TRT). The effect was reported as regression coefficients for the interaction term with 95% confidence intervals and could be interpreted as the mean difference in change in outcome score between the intervention and control groups after adjustment for potential differences in outcome at baseline. The use of linear mixed

models with data in long format allowed for inclusion of baseline data for participants who dropped out during the intervention, which is in line with the intention-to-treat (ITT) principle. Estimates will be unbiased as long as follow-up data are missing at random. Since group dynamics and other aspects of the group members could cause correlations between individuals within a group, we did additional analyses with linear mixed effects with random intercept and slope for group membership in addition to random intercept for individuals.

Additional longitudinal analysis was performed to study time trends in the outcome during the intervention phase and the first four weeks after the last intervention session. In these analyses we also included the individuals in the control group, since they also received the intervention after a delay.

11.17. Data Management and Monitoring

The core study team for CHART involved in this RTC (https://www.uib.no/en/generalpractice/chart) consisted of the principal investigator of the study, three other senior researchers, two master's students and three PhD students (one of whom was mainly responsible for this part of the study). The core study team and the municipality of Bergen met regularly to ensure adherence to protocol, study quality and ethical conduct, and followed the overall progress of the interventions. Furthermore, both health practitioners and partnering interpreters involved in TRT intervention were trained by the Centre for Crisis Psychology and had frequent contact with the municipality and the university to ensure fidelity to their intervention. The interpreters attended a course to learn the language/terminology used during the PAAI in advance of the interventions. Data collection and plotting was the responsibility of the University of Bergen. Double data entry was conducted and was stored on a secure data server. Until analysis, data cleaning with range checks for data values was performed. There was no independent auditing or data monitoring committee.

The CHART study had an external reference group consisting of national and international stakeholders, including representatives' members. We conducted one

international meeting in Bergen, including the whole team each year (partially digital in 2020).

11.18. PARTICIPATION IN PAAI

We recruited a total of 180 persons for the interventions. Among the participants, 101 of them had a predominant burden of pain symptoms and were included in the PAAI trial, of which 50 were randomized to the intervention group and 51 to the control group. The first session was attended by 38 (76%) participants from the intervention group and 34 (67%) from the control group who filled out the questionnaire (Q1a) on the starting day of the group sessions. Eight weeks later, at the end of the group sessions, 31 (62%) participants participated in the intervention group and 24 (47%) in the control group. Participants completed the same questionnaire (Q1b). After 12 weeks, 27 participants from the intervention group (54% participation rate) and 23 participants from the control group (47% participation rate) answered the same questionnaire (Q1c). In **(figure 7)**, the CONSORT flow chart showed the number of participants who attended the PAAI sessions. Semi-structured interviews were conducted for 17 participants from the intervention and the control groups: six of them had dropped out before or during the sessions and 11 of them had completed the intervention.

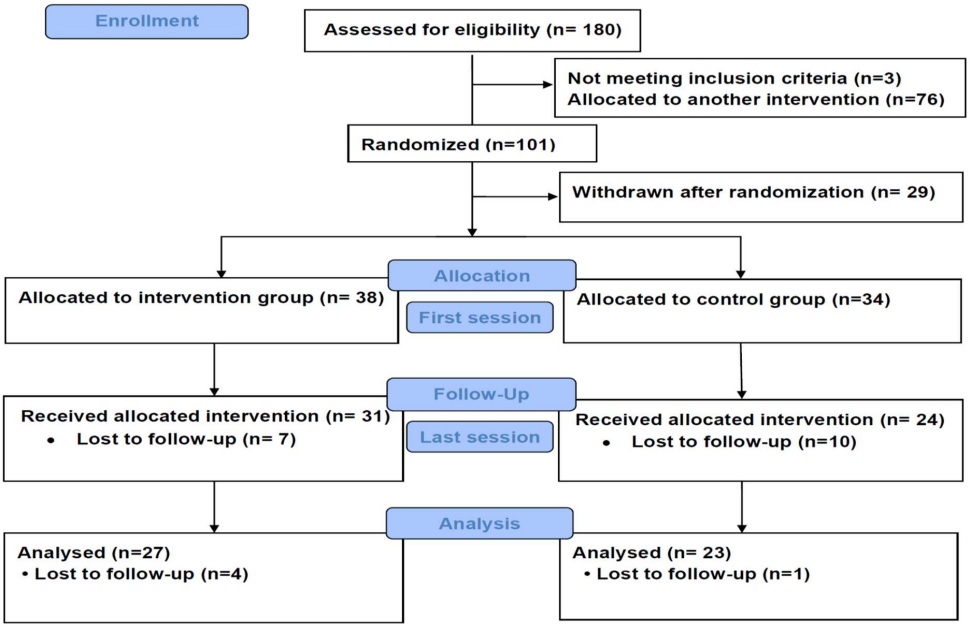

Figure 7. *CONSORT flow chart for PAAI*

11.19. PARTICIPATION IN TRT

Among the 180 persons recruited, 76 participants had predominant burden of mental health symptoms. Of them, 38 persons were randomized to the intervention group and 38 to the control group, but only 26 participants (68%) from the intervention group and 28 participants (74%) from the control group attended the first session and completed the questionnaire on the day the group sessions started (Q1a), as shown in the CONSORT flow chart **(figure 8)**. Six weeks later, 23 participants (61%) from the intervention group and 13 participants (34%) from the control group completed the same questionnaire (Q1b). After twelve weeks of the intervention, 23 participants from the intervention group (61%) and 14 participants from the control group (37%) completed the questionnaire (Q1c). Semi-structured interviews were conducted for 21 participants from the intervention and control groups: nine of them had dropped out before or during the sessions and 12 of them had completed the intervention. This qualitative material was nevertheless not included in this thesis.

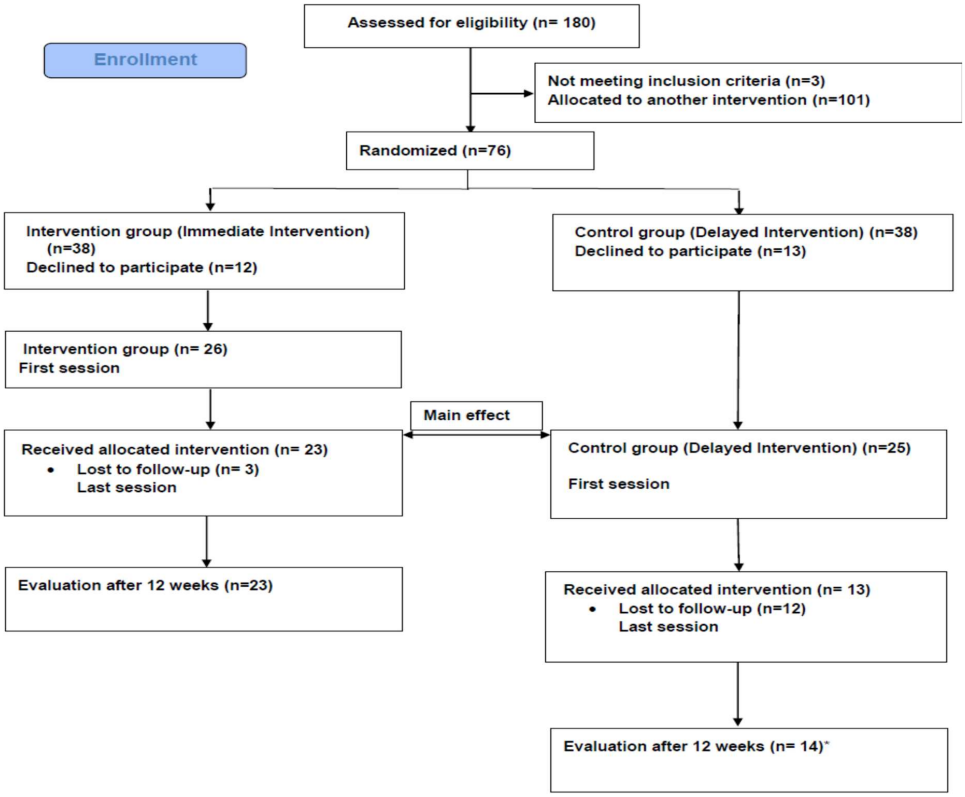

Figure 8: *CONSORT flow chart of TRT*

The number of participants who attended the PAAI and TRT sessions in each group (intervention and control) are summarized gender-wise in Table 4.

	PAAI				TRT			
	Intervention		Control		Intervention		Control	
	M	F	M	F	M	F	M	F
Baseline, n	31	19	30	21	26	12	22	16
S1, n (%)	24 (77)	14 (74)	18 (60)	16 (76)	16 (62)	10 (83)	19 (86)	9 (56)
S2, n (%)	17 (55)	13 (68)	9 (30)	13 (62)	13 (50)	8 (67)	10 (45)	5 (31)
S3, n (%)	14 (45)	7 (37)	8 (27)	12 (57)	13 (50)	9 (75)	7 (32)	5 (31)
S4, n (%)	13 (42)	11 (58)	6 (20)	11 (52)	14 (54)	6 (50)	7 (32)	4 (25)
S5, n (%)	12 (39)	7 (37)	4 (13)	13 (62)	12 (46)	8 (67)	9 (41)	3 (19)
S6, n (%)	12 (39)	9 (47)	5 (17)	13 (62)	15 (58)	8 (67)	10 (45)	3 (19)
S7, n (%)	12(39)	6 (32)	4 (13)	10 (48)				
S8, n (%)	19 (61)	12 (63)	9 (30)	15 (71)				

Table 4: *Number of participants who attended the PAAI and TRT sessions in each intervention and control group, by gender*

Note: PAAI: Physiotherapy Activity and Awareness Intervention, TRT: Teaching Recovery Techniques, M: male group, and F: female group, S: session. The colours represent participants' attendance: green is attendance ≥ 66.5%, yellow is 33.5-66.5%, and red is ≤33.5%.

12. RESULTS

Both the interventions were carried out as planned and we managed to recruit the number of refugees that we had calculated as necessary to find an effect, as explained in statistical methods. In terms of the balance between the intervention and control groups, our trial was a success. We did not detect any harm to the participants. The main findings of this thesis are as follows.

The ITT analyses showed no clear effect of the PAAI intervention in either the pain levels measured by BPI or improvement in the mental health measured by IES-R and GHQ-12. The TRT showed a significant effect on general mental health as measured by GHQ-12, but there was no effect of TRT on PTSD-related symptoms measured by IES-R 22 or on pain levels measured by BPI. For some of the analyses, the reason for the lack of effect by ITT was improvement in both the intervention and the control groups. In the qualitative analysis, the participants described the sessions as social support points. They appreciated the interventions as a meeting point for their group. The intervention provided the participants with tools to apply in everyday life, which increased their self-confidence and gave them a sense of control over their own health. The participants were able to identify facilitators and challenges because of their involvement in the intervention. Despite the lack of effect by ITT, this study adds to the evidence base necessary to plan targeted and effective healthcare services for refugees suffering from chronic pain and mental health symptoms. In addition, our study highlights the challenge of evaluating complex interventions adapted to a group with special needs.

Table 5 presents the demographic of the persons recruited for PAAI and TRT and those participants with only baseline measurement (dropouts).

		PAAI		TRT	
		Follow-up	Dropouts	Follow-up	Dropped out
Total, N		65	36	51	25
Age (years), Mean (SD)		38 (10.3)	34 (12.8)	34 (10.3)	29 (10.1)
Low health literacy, N (%)		36 (55)	14 (39)	22 (43)	14 (56)
Female, N (%)		28 (43)	12 (33)	17 (33)	11 (44)
Stayed in a transit country on the way to Norway, N (%)		46 (71)	14 (39)	38 (75)	11 (44)
Education (years), Mean (SD)		8.6 (4.2)	11.4 (3.9)	9.8 (4.6)	10.6 (4.6)
Exposure to stressful events, N (%)		44 (68)	24 (67)	51 (100)	25 (100)
Physical pain more >6 months		50 (77)	25 (70)	27 (53)	5 (20)
Never exercise		38 (58)	11 (31)	28 (55)	12 (48)
BPI (Pain intensity (4-40)) Mean (SD)		6.0 (1.9)	5.4 (2.3)	3.8 (1.7)	3.1 (1.9)
IES-R (0-88), Mean (SD)	Intrusion (8-32)	9.4 (7.6)	9.3 (7.9)	17.0 (6.3)	16 (5.6)
	Avoidance (8-32)	9.5 (7.9)	10.7 (7.9)	19.0 (4.9)	17.7 (5.5)
	Hyper-arousal (6-24)	7.4 (5.7)	7.0 (5.8)	13.0 (4.9)	11.0 (4.2)
GHQ-12 (0-36)		13.4 (6.1)	11.2 (6.7)	16.7 (7.4)	14.7 (5.1)

Table 5. Group comparisons on the characteristics of follow-up and dropouts for PAAI and TRT

12.1. Effect of PAAI Intervention

Paper II presents the results of the PAAI RCT. Of the 101 participants allocated to the PAAI RCT, 65 had follow-up data (31 in the intervention and 34 in the control groups). In this study, 68% of participants were exposed to traumatic events, and all presented pain. About 12% registered high levels of mental health symptoms. Group comparisons on the characteristics of follow-up and dropouts of PAAI are presented in (Supplementary 9). The ITT analysis showed no effect of the intervention on either pain levels or mental health symptoms. The results are presented in Table 6.

	Intervention, n=50			Control, n=51			Intervention effect	
	Baseline (Q0). Mean (SD)	Last session (Q1b). Mean (SD)	p-value*	Baseline (Q0). Mean (SD)	End of waiting period (Q1a). Mean (SD)	p-value*	Coefficient B (95% CI) **	p-value
BPI	5.8 (1.9)	5.5 (2.1)	0.14	5.8 (2.3)	5.5 (2.1)	0.07	0.03 (-0.91, 0.96)	0.95
IES-R	25.9 (20.0)	31.2 (15.8)	0.10	26.7 (19.6)	25.8 (19.3)	0.90	4.8 (-3.7, 13.4)	0.27
GHQ-GHQ12	12.7 (6.7)	11.4 (6.1)	0.03	12.5 (6.1)	11.7 (5.3)	0.05	-0.4 (-3.1, 2.3)	0.76

Table 6: *Effect of PAAI intervention on the primary and secondary outcomes*

*Note: ITT analyses using linear mixed models, *Paired t-test for within group change. **Regression coefficient for interaction term between group allocation and time.*

Despite this lack of effect as ITT, there was longitudinal improvement in mean levels of BPI, IES-R and GHQ-12, separately, for males and females for all participants of PAAI (n=101), as shown in (**figure 9)**. For BPI and GHQ-12, in both genders, the test for linear change with week treated as a continuous covariate was significant showing significant reductions in BPI and GHQ-12 from the first session (week 0) to the last session (week 8). The calculation in week 12 was also significantly reduced compared to week 0. The longitudinal changes in outcomes of PAAI for intervention and control groups, from first to last sessions and four weeks after the last session for intervention and control groups combined (n=101) using liners mixed models, are presented in (Supplementary 10).

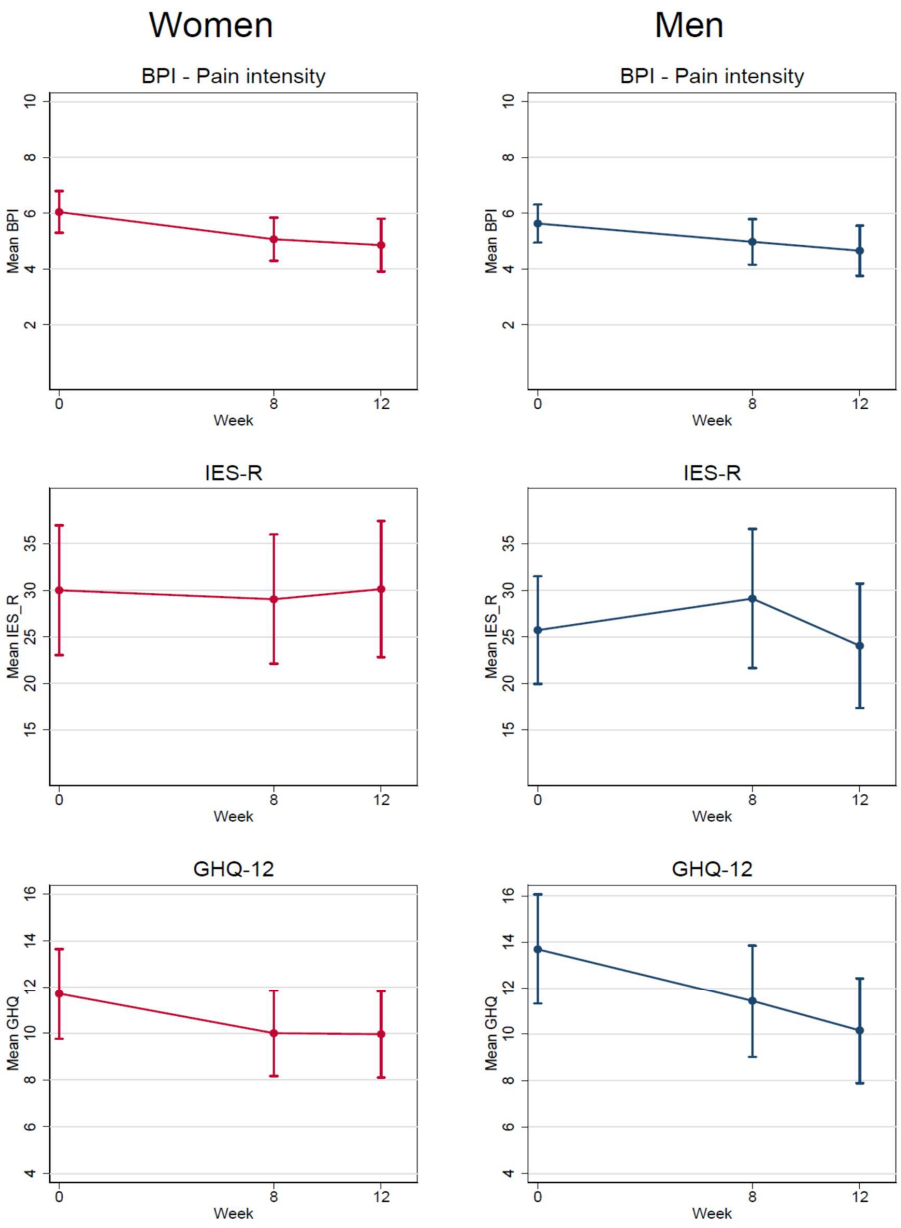

Figure 9. *Levels of BPI (pain intensity), IES-R and GHQ-12 for all participants*

The qualitative interviews conducted revealed three main themes. First, the intervention was highly appreciated by the participants as a gathering and social place for their group to meet and address the common challenges of being newcomers in Norway. Second, the intervention provided the participants with strategies to apply to everyday life, such as learning to concentrate on the body, which helped them with sleep, posture or using precise movements in their daily lives. Such elements increased participants' self-confidence and gave them a sense of control over their own health. Third, the participants identified the facilitators and barriers to participation in the intervention. A good therapist, a good translator, a supportive atmosphere, and the prospect of breaking daily routines were discussed as some of the facilitators. Conflicts over timings, especially if they clashed with family duties and medical appointments, particularly for women, were barriers to attending the interventions and could add some degree of stress. Gossip from others, particularly those who were unhappy, was also considered a barrier (154). Gender was the most important difference found in the groups' dynamics.

12.2. Effect of TRT Intervention

Paper III presents the results of the TRT RCT. Among the 76 participants, 51 had follow-up data (26 in the intervention and 25 in the control groups) and 25 dropped out. Group comparisons on the characteristics of follow-up and dropout of TRT are presented in (Supplementary 11). The ITT analysis showed that there was a significant effect of the TRT on general mental health measured by GHQ-12. However, there was no significant effect when measured by IES-R 22, or on pain when measured by BPI. The results are presented in Table 7.

	Intervention, n=38			Control, n=38			Intervention effect	
	Baseline (Q0) Mean (SD)	Last session (6 weeks) (Q1b) Mean (SD)	p-value*	Baseline (Q0) Mean (SD)	End of waiting period (6 weeks) (Q1a) Mean (SD)	p-value*	Coefficient B (95% CI) **	p-value
IES-R	47.8 (13.6)	40.3 (12.8)	0.002	47.0 (13.8)	41.0 (17.0)	0.014	-1.3 (-8.7, 6.2)	0.74
GHQ-12	17.1 (6.5)	10.7 (5.2)	<0.001	15.0 (7.0)	14.0 (7.0)	0.253	-3.8 (-7.2, -0.4)	0.02
BPI	3.6 (1.9)	3.6 (2.2)	0.594	3.6 (1.7)	3.6 (2.0)	0.687	-0.01 (-0.99, 0.97)	0.98

Table 7. *Effect of TRT intervention on the primary and secondary outcomes*

*Note: ITT analyses using linear mixed models, *Paired t-test for within-group change, **Regression coefficient for interaction term between group allocation and time.*

Also, for TRT there was longitudinal improvement, i.e. improvement with time independent of the intervention, in mean levels of IES-R 22, GHQ-12 and BPI, including the intervention and post-intervention periods for the control group and six weeks later, as shown in **(figure 10)**. There was a significant reduction from the first session (week 0) until the last session (week 6) for men and women together in IES-R and GHQ-12. Also, the measurements were significantly reduced in week 12 compared to week 0 as shown in (Supplementary 12). The test for linear change was significant for men and women together. However, there was a significant reduction in pain scores for men alone compared to women alone or both combined.

The results of the qualitative interviews of this RCT were presented in a separate master thesis linked to the CHART study (154). The participants also regarded this intervention as a place to meet other Syrians, form new friendships and provide social support to other group members. The participants claimed that the group experiences helped them normalize mental illness. The intervention was a place to share feelings and communicate with others, as well as a break from everyday routines. The participants learned that their symptoms are typical responses to stressful experiences and that they're not alone in coping with these issues, which comforted and encouraged them. Learning how the body reacts to potentially stressful events provides information that

can help in identifying symptoms and, as a result, be the first step towards recovery. This will start empowering systems to help people find solutions (154).

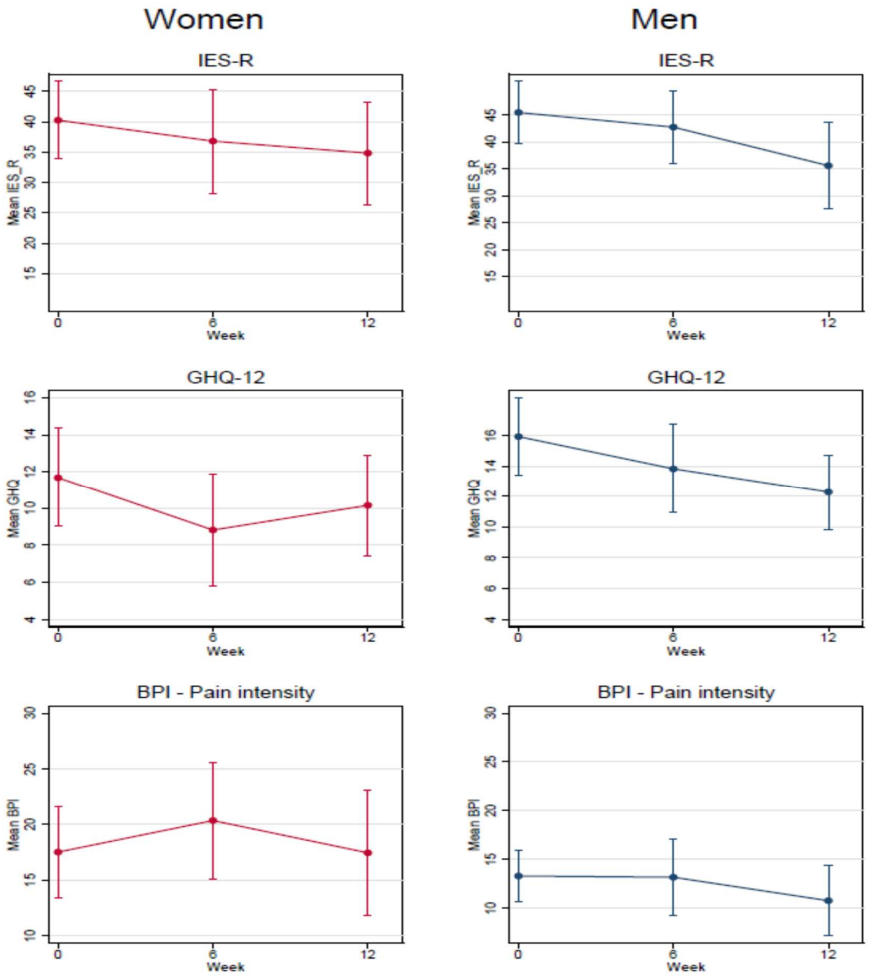

Figure 10. *Levels of GHQ-12, IES-R and BPI (pain intensity) for all participants*

Note: Week 0= first TRT session, week 6= last TRT session and week 12= six weeks after last session, Interventions, and controls (after participating in the intervention waiting list) are presented together, stratified by gender. Mean scores with 95% confidence intervals.

13. DISCUSSION

13.1. DISCUSSION OF THE RESULTS

13.1.1. THE EFFECT OF PAAI

This study adds new essential information to the field of research on health among refugees, which has previously focused on mental health problems. In spite of not being able to show a significant effect of the group physiotherapy intervention (PAAI) on reducing either pain disorders or improving mental health among adult Syrian refugees after 8 and 12 weeks, the symptoms improved with time and the participants were happy with the intervention and confirmed that they had learned important tools to be used in their daily life.

With regard to other research similar to our study, we found only one recent pragmatic trial that was conducted among traumatized refugees with PTSD in Denmark, in which participants were randomized to receive either individual BBAT or two other forms of individualized therapy. Similar to us, by using ITT analysis, they found no significant effect of the intervention on mental health, but a small significant improvement in the longitudinal analysis (155). This suggests that PAAI does not specifically target trauma or mental health. The Eye Movement Desensitization and Reprocessing (EMDR) and the Emotional Freedom Techniques (EFTs) interventions can specifically target traumatic events (156), but they have not been reported to help with pain disorders, which was the main outcome of our study.

After 8 and 12 weeks, our study showed no significant effects of the intervention itself on pain relief, which could be due to many reasons. Our results showed that 52% and 45% of the intervention group and the control group, respectively, said they never exercised prior to the intervention. This is another difficult obstacle to overcome and may need a different type of intervention. Moreover, by comparing the participants lost to follow-up, it was established that the participants who had a longer migration route to Norway were less physically active and had lower education and were more likely to disengage from the intervention. The possibility that the participant selection process

involved a high proportion of treatment-resistance (participants could have tried and failed different treatments before starting this one) could have contributed to a selection of patients that were difficult to help. Even though we used a group of advisors for the implementation of the interventions, the intervention may not have been sufficiently adapted to our participants and their situations, which could be reflected on the relatively high dropout numbers. The qualitative interviews indicated that participating in the intervention could clash with other activities and could add some degree of stress. Being occupied and stressed with daily routine activities could have influenced participation.

Because of what is known as regression to the mean, when measuring something that fluctuates and measured at its maximum, any later measure would be more likely to be lower. In addition, many will seek help and might be more interested to take action such as joining a group intervention at a point when, for example, their pain and/or mental health symptoms are high. While we used validated instruments to measure pain, pain can fluctuate, which means that the participant may have moderate pain one day, no pain the next day, and then mild to severe pain (157). Therefore, we might have chosen the participants at a time when they were experiencing a very high level of pain.

Findings of a recent systematic review indicate that physical activity may be a valuable supplement to standard treatment for people with mental health symptoms (158). Our results in the longitudinal analysis indicated that the effect of PAAI on mental health was more positive using GHQ-12 compared to IES-R scores. This mean that PAAI could be best suited to improve mental health among individuals with milder mental health symptoms. However, there was no sufficient power to stratify the analysis according to symptoms. Therefore, more research in this area should be done as mild symptoms of mental health are very prevalent.

In line with our results, in the longitudinal analysis where no gender differences were found, despite the slight difference in dynamics observed between female and male groups, two previous studies showed that the effect of BBAT did not differ by gender

among traumatized refugees in Denmark and among general psychiatric patients in Sweden (159, 160).

In Paper II, we discuss other factors that may define why we did not find any intervention effect. The intervention time and the limited duration of the sessions, each lasting just one hour, could have been inadequate. PAAI has not been used before and was developed for use in CHART.

Despite the fact that the PAAI intervention had no effect on pain disorder and mental health symptoms, there was a statistically significant improvement in both groups with time. This might be due to the Hawthorne effect, where participants have a desire to have a trait to perform better when being observed (161). The findings of our semi-structured interviews indicate that the group sessions were positive in many ways for the participants, including the social and instrumental ones. The qualitative results are particularly interesting, pointing to improvement in the quality of sleep, self-confidence, and stress reduction, which could decrease the level of pain (162). These results were in line with Swedish studies using BBAT (162, 163).

13.1.2. THE EFFECT OF TRT

To our knowledge, this is the first trial studying the effect of self-help group intervention using TRT among adult refugees with mental health symptoms.

The TRT, evaluated by GHQ-12, improved the general mental health of Syrian refugees, but did not improve mental health symptoms when assessed by IES-R 22. However, in all mental health results, both the intervention and control groups showed a positive trend in longitudinal analyses during the intervention process. The TRT intervention did not help in reducing chronic pain.

The TRT was initially designed for children, and there is no previous research with which to compare our findings. A new adult TRT manual was being created, but only after our research had already begun. A review of the interventions targeting migrants

(e.g. CBT, NET, EMDR and PM+) found that there was a positive effect of these interventions, but it also identified research gaps in the existing literature (138). Previous RCT studies using TRT among Palestinian adolescents found a little effect of TRT on PTSD measured by the Exposure to War Stressors Questionnaire (EWSQ) and the 13-item Children's Revised Impact of Event Scale (CRIES-13). However, there was no effect of TRT on depression measured by the Depression Self-Rating Scale (DSRS) (137). An Australian RCT study among traumatized young refugees showed an effect of TRT on depression measured by the DSRS (164). Further, an RCT study using TRT among Palestinian war-affected children found that there was a little effect of the intervention on reducing mental health symptoms. The Strengths and Difficulties Questionnaire (SDQ), CRIES-13 and DSRS were used in assessment (165). In line with our results, TRT showed an effect on general mental health when assessed by GHQ-12, but not on mental health symptoms when assessed by IES-R 22 or on pain assessed by BPI. The fact that several studies find effects depending on the instruments used reflects the complexity of the symptoms and personal situations under study which are not always easy to quantify.

Variations in the effect, depending on the questionnaires used, could help us understand the impact of the intervention on the participant. Mental health related to long post-traumatic experiences was assessed by the IES-R items (166), while the GHQ items determined the current state of a person in terms of symptoms within the common emotional disorders (i.e. depression and anxiety) and daily functioning problems (167, 168). As such, the effect of TRT in GHQ-12 might imply that this intervention better targets mental health related to everyday life compared to symptoms clearly related to previous traumatic events.

Several possibilities might explain why we did not find the effect of TRT on the IES-R scale: fluctuating trauma symptoms, selection of the participants at a time when their symptoms were not high enough at the baseline, and regression to the mean decreasing the IES-R scores in both groups (which might be less obvious with symptoms assessed by the GHQ, as shown in longitudinal analyses in figure 10).

There was no confirmation of our hypothesis of a secondary influence on pain levels. This may be because the intervention time was too short or because of a real lack of effect. Another potential reason could be that a high degree of pain was not an inclusion criterion for our study.

In some intervention sessions, attendance in TRT was low, particularly for female groups. Earlier research has pointed to the stigmatizing attitudes in mental healthcare and the busy schedules of the refugees (e.g., regular events like compulsory school and other activities) as deterrents (169, 170) . Other reasons for low attendance could be perceived adverse rumours among participants in the school, cultural attitudes to mental health and Ramadan. One of the most important rumour was that the Norwegian Barnevern (Child Protection Services) will take the child from the parent due to mental health problems.

13.2. Methodological Considerations

We conducted a double-armed RCT, evaluating the effect of the two separate interventions among adult Syrian refugees. The RCT is considered the gold standard in clinical research because of the trial's ability to minimize selection bias and the risk of confounding factors that can affect the results. Preferably, we should use a full factorial design, including one group receiving both interventions, to estimate the effect of TRT on pain, the effect of PAAI on mental health problems, and the potential effect of the interaction between TRT and PAAI. However, that would have required a larger sample size and the number of Syrian refugees with pain or mental health symptoms in Bergen might not have been sufficient to make this possible. In fact, to be able to achieve the numbers needed, we recruited Syrian refugees and asylum seekers from Bergen and adjacent municipalities. In this way, and working tightly with the community, we managed to get the number of participants we required to be able to detect the effect of the interventions, including an estimated dropout rate of 25%–30% based on previous experiences. In the CHART team, at the beginning of the study, for the practical

implementation of the interventions, we requested user involvement in the development of the interventions, as explained in detail in the Section 3.2 (142).

Internal and external validity concepts are used to evaluate the trustworthiness and generalizability of the study results. The internal validity is the degree to which a study establishes a reliable relationship between cause and effect so that results are not influenced by other factors or variables. The external validity refers to how generalizable the results are (171). An RCT design offers and supports a strong internal validity. Allocation bias was reduced by randomization and confounding was thus minimized. Therefore, internal validity was improved by the random allocation of participants to treatment (172).

The ITT analysis was used to analyse the results, which minimizes potential selection biases. This means that all randomized participants are included in the statistical analysis and evaluated according to the group to which they were initially assigned, regardless of the treatment they received. Not all the participants in the RCT finished their follow-up (173). Also, the external validity was promoted by the ITT analysis since it is a pragmatic method aimed to evaluate the effectiveness of the intervention in such trials (172).

The effect of the TRT and PAAI interventions was assessed by comparing the scores from the last session of the intervention group (six or eight weeks) with the scores from the first session (right before the beginning of the session) of the control group. This is usually done to avoid any changes in the IES-R, GHQ-12 and BPI answers in the control group that could be influenced once the session is completed.

13.3. Strengths, Limitations and Generalizability

First, in terms of the balance between the intervention and control groups, our trial was a success. In a population that is considered difficult to recruit, we managed to get the right number of participants to be able to detect an effect because we had planned on a 25% to 30% dropout rate based on the previous experience of physiotherapists and

psychologists. Second, the Arabic background of the resource persons involved in the project, and regular meetings with the interpreters to discuss vocabulary beforehand, gave us a resource pool of persons who were prepared to reduce language barriers. This allowed us to adapt and carry on despite any challenges such as illness among interpreters. Third, good collaboration between the first author and both the physiotherapists and psychologists and the participants was key to facilitating the implementation of the sessions and encouraging participation. In addition, the strong and well-developed collaboration between the various organizations and municipalities in Norway facilitated the recruitment of participants and the implementation of the intervention. Fourth, to understand the effect of the intervention, the complementary use of both qualitative and quantitative approaches gives us a deeper understanding of the need for potential interventions to be applied in the real world (105). Fifth, the close monitoring of the sessions through observation allowed us to understand the gender-based differences in dynamics between groups that could be further explored through statistical analyses. Lastly, we decided to include only refugees from Syria, the largest migrant group in Norway since 2015, in collaboration with the municipality of Bergen, because a variety of groups could have complicated language translations in the sessions.

The delayed intervention design (control group) was considered to be the only ethically appropriate approach, which often made it difficult to determine potentially delayed effects that might occur at a later stage but were not present immediately after the intervention. Our study does not include findings tested clinically and relies on self-reported data. The effect of ITT analysis was possibly limited by a low attendance rate at the PAAI and TRT sessions. While we had a consultant group to help us adapt the intervention to the lives of the participants, the key reasons for participants dropping out of the sessions were (a) the mandatory educational activities for newly resettled Syrian refugees and (b) childcare issues. Thus, the chance of selection bias may increase. It is common in this type of study to have a low attendance rate, even lower than in our study (155, 174).

Furthermore, outcome measures were self-reported in our research, and neither the participants, the outcome assessors, nor those conducting data analysis were blinded. Nevertheless, we did our best to review the process in all its parts for consistency.

The PAAI interventions among Syrian refugees could be generalized for other refugee populations with pain disorders. The TRT was developed for children and not evaluated for adults, but a manual for adults is now under evaluation, and should be used if the TRT intervention is rolled out clinically for adults. Taking this into account, we believe our research may also be generalized for other refugees suffering from pain disorders and/or general mental health symptoms.

14. CONCLUSION

This thesis improves the understanding of the effects of group physiotherapy and self-help groups using TRT among vulnerable groups with pain disorders or mental health symptoms. Our research adds to the evidence base needed to prepare targeted and reliable healthcare programmes for a vulnerable population, while also highlighting the difficulty of assessing complex approaches tailored to a particular population. Our study indicates that the PAAI had no effect on either chronic pain or mental health symptoms. However, participants were pleased with the intervention, reported other positive experiences and no side effects. Further, the self-help group intervention using TRT showed improvement in general mental health symptoms among adult Syrian refugees but had no clear effect on trauma symptoms or chronic pain. To achieve the full potential of TRT, higher participation rates may be necessary, which might need better adapting to participants' daily lives.

For the receiving country, welcoming refugees is indeed a winning project that needs to focus on common health problems like pain and general mental health symptoms. Refugees will begin productive lives in their host countries if they are provided the right to work, health and education. The quicker they can integrate into work, the quicker they become active members of society.

15. Implications and Perspectives for the Future

Despite not having found effects by ITT on the primary outcomes in any of the interventions, the qualitative study interviews indicate that it might be possible to further develop these interventions to their full potential in terms of improving mental health and chronic pain. In addition, this will allow some leisure and social time for the refugees, breaking the daily routine, which helps them to integrate, acclimatize and overcome some of the challenges of being in a new country.

Future studies should also look at how the interventions can be adjusted to refugees' own perceptions of the concept of trauma and psychosocial distress and be developed in close collaboration with healthcare providers. Cost-effectiveness should also be considered and worked out. Once improved, it could be useful to look at the effect of such interventions on other groups of migrants.

Once developed and tested, training staff that is in direct contact with the refugee population on the possibility of group interventions might also be necessary to improve mental health and/or pain disorder for this group. In addition, information on the existence of such possibilities should be provided to the refugees as part of the language and social education or introductory programmes that are established for newcomers in high-income countries.

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17. APPENDIX

Paper I

Paper II

Paper III

Supplementary files (1-12)

1. Informed consent form-questionnaire used at base line and at the beginning of the interventions (in English, available in Arabic upon request)
2. Informed consent form-personal interview (in English, available in Arabic upon request)
3. Poster placed on the doors and entrances of schools, shops and waiting rooms of practices of medical clinics (in English, available in Norwegian and Arabic upon request)
4. Letter send to general practitioners, physiotherapists, and psychologists (in English, available in Norwegian upon request)
5. SMS send to all Syrian participants who went to school (in English, available in Arabic upon request)
6. Letter to the director of the school (in English, available in Norwegian upon request)
7. Pre-structured scheme used to take notes on when and how the interventions were implemented and carried out
8. Table: Number of interviews for participants by gender and duration of interview
9. Table: PAAI sensitivity analyses: group comparisons on characteristics of follow-up and dropped out
10. Table: Change in outcomes in PAAI intervention from first to last sessions and four weeks after last session

11. Table: TRT sensitivity analyses: group comparisons on characteristics of follow-up and dropped out
12. Table: Change in outcomes in TRT intervention from first to last sessions and four weeks after last session

Additional files (1- 6)

1. CHART Questionnaire 0 used at baseline (in English, available in Arabic upon request)
2. CHART Questionnaire 1 used at the first and last sessions of the treatments and 12 weeks after the first session (in English, available in Arabic upon request)
3. Questions used for evaluation of PAAI group intervention
4. Questions used for evaluation of TRT group intervention
5. Ethical approval from the Regional Committee for Medical and Health Research Ethics of South East Norway (REC South East Norway)
6. Other publications related to the CHART project

Paper I

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Trials

STUDY PROTOCOL Open Access

Two interventions to treat pain disorders and post-traumatic symptoms among Syrian refugees: protocol for a randomized controlled trial

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Abstract

Background: There is a high prevalence of pain and post-traumatic symptoms among refugees and feasible interventions to manage these are needed. However, knowledge about the effect of physiotherapy and psychological group interventions among refugees is scarce. Our aim is to determine whether two different interventions, the Physiotherapy Activity and Awareness Intervention (PAAI) and Teaching Recovery Techniques (TRT), reduce pain and post-traumatic symptoms among refugees from Syria living in Norway.

Methods/design: Syrian adults with either pain disorders or post-traumatic symptoms, or both, will be recruited to this randomized control trial. The trial will include two separate interventions: participants with dominating pain symptoms will be assigned to the PAAI; and those with a predominance of post-traumatic symptoms will be assigned to the TRT intervention. Participants will be randomized to either the immediate intervention group or the delayed intervention group, for each of the interventions (PAAI and TRT). A minimum of 68 participants will be recruited for the PAAI and 78 participants for TRT, in order to detect clinically and statistically significant symptom improvement, assuming 25–30% attrition after recruitment. The main outcomes for the analyses will be pain intensity measured by the Brief Pain Inventory questionnaire and the scores of the Impact of Events Scale — Revised. The effect will be evaluated at the end of interventions lasting 8 weeks (PAAI) and 6 weeks (TRT) using the same instruments after the end of the intervention, and again 4–6 weeks later. Additionally, a qualitative evaluation will be conducted through an embedded process evaluation and personal interviews with participants after each of the interventions is finished.

Discussion: Our study will determine the feasibility of the implementation of two different interventions and the effect of these interventions among refugees from Syria with pain disorders and/or post-traumatic symptoms.

Trial registration: Clinical Trials.gov, NCT03951909. Retrospectively registered on 19 February 2019.

Keywords: Randomized controlled trial, Mental health, Chronic pain, Teaching Recovery Techniques, Physiotherapy, Refugee

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Background and rationale

Both chronic pain and mental health symptoms can be a consequence of traumatic events [1, 2]. At the beginning of 2019, according to the United Nations High Commissioner for Refugees (UNHCR), 70.8 million displaced persons due to war and violent conflict were registered worldwide, of which 25.9 million were refugees. Syrians are one of the growing groups that have fled to Europe since the war began in 2011 [3, 4]. Norway is no exception, with more than 30,000 Syrian refugees living in the country by the end of 2018 [5–8]. Many refugees have been exposed to stressful events or situations that can lead to persistent distress [9]. As a consequence, the presence of pain disorders and mental health symptoms is common, both of them often in combination within the same individual [10, 11].

The complex relationship between torture, pain and other aspects of the individuals' experience before and after migration has profound impacts on the everyday lives of many refugees [12]. Pain has been identified as a predictor of emotional distress among refugees [13], but there is a scarcity of population-based data about pain disorders among refugees from Syria. According to a Norwegian study, 76% of the traumatized refugees attending an outpatient clinic experienced chronic pain [14].

Mental problems of various types and degrees are prevalent among refugees, including Syrians. In Lebanon during 2011–2013, 44% and 61% of Syrian refugees reported depression, and some of them also loneliness, in two similar studies [15, 16]. In 2014, 54% of Syrians accessing International Medical Corps facilities in Syria and neighboring countries suffered severe emotional disorders, including depression and anxiety [9]. Among the Syrian refugees resettled in the USA, a high prevalence of post-traumatic stress disorders (PTSD) (32%), anxiety (40%) and depression (48%) has been reported [17].

Health care services for refugees during flight and in host countries shortly upon arrival are either non-existent, inadequate or insufficiently available, especially regarding chronic pain and mental health problems [18]. Inadequate health care for refugees can worsen their symptoms and lead to chronicity [10]. Once established in a host country, the national health services in most high-income countries are obliged to offer health care services to refugees. However, the lack of evidence regarding the best treatment choices for this population, together with limited resources, may compromise the health services provided to refugees. In addition, treatments are often only entitled to those with formally established diagnoses. However, many refugees who do not have enough symptoms for a formal PTSD or chronic pain diagnosis might still have symptoms like headaches or flash backs that go unmanaged and impede their learning of a new language and integration into society. It has been suggested that group treatment could be an approach to maximize the effect of the treatment for coping with symptoms among traumatized refugees, as well as a means to increase social interaction and well-being among participants [19].

The evidence on group-based physiotherapy for chronic pain among refugees is scarce. As far as we know, only a study in progress in Denmark has used mixed physical activity and basic body awareness therapy to reduce chronic pain for refugees with established PTSD [20]. A combination of psychomotor and general physiotherapy exercises is often used in Norway and other Nordic countries in group therapy, as this enables the health professional to recognize and normalize the participants' emotions and movement patterns, capturing and preserving the individual treatment needs within the group, at the same time as having an overview of the social interactions [21]. However, the adequacy or effect of this therapy has not been well studied for refugees. The Physiotherapy Activity and Awareness Intervention (PAAI) package was adapted for this study based on this combination of psychomotor and general physiotherapy, and grounded on the extensive experience with immigrant patients of the physiotherapists in the team and according to users' recommendations.

Teaching Recovery Techniques (TRT) is a self-help group intervention designed and evaluated for children by the Children and War Foundation for use on subjects exposed to war or natural disasters [22]. TRT is built to meet the needs of a large number of traumatized refugees who require interventions for mental support. It is based on the principles of cognitive behavioral therapy and on evidence-based methods for treating trauma. The intervention focuses on three main groups of symptoms following severe traumatization, namely invasive sensory impressions, bodily activation and avoidance. TRT has shown significant effect in terms of reducing the aforementioned symptoms among children surviving catastrophes and adolescent asylum seekers in Europe [23]. Among adolescents in Palestine, TRT significantly reduced post-traumatic stress symptoms and was evaluated as a cost-effective intervention [24]. However, the effect of TRT on adult refugees with post-traumatic symptoms has not been studied.

Taking the previous into consideration, there is a need to develop and evaluate techniques and methods to adequately deal with adult refugees with chronic pain and post-traumatic symptoms.

Objectives

The main objective of this project is to evaluate the effect of two different interventions, separately, among adult Syrian refugees with pain and/or post-traumatic symptoms:

- The Physiotherapy Activity and Awareness Intervention (PAAI) in reducing the degree of pain, and secondarily in reducing post-traumatic symptoms (if present)
- The Teaching Recovery Technique (TRT) group intervention in reducing the degree of post-traumatic symptoms, and secondarily in reducing the degree of pain (if present)

Methods

Study design

This is a 2 × 2 armed randomized control trial (RCT) to study the effect of two different interventions for treating pain and post-traumatic symptoms (Fig. 1). Participants with dominating pain symptoms will be assigned to the PAAI and those with a predominance of post-traumatic symptoms will be assigned to the TRT intervention. Participants within each of the arms are randomized to either the immediate intervention group or the delayed intervention group, which will receive the same intervention but at a later time point. The study protocol follows the SPIRIT recommendations for intervention trials (Fig. 2, Additional file 5).

In addition, to examine the process of how the interventions improve health, a qualitative embedded process evaluation using personal observation of the intervention groups and individual semi-structured interviews will be conducted to gain an in-depth understanding of the mechanisms of action and key contextual variables affecting the intervention.

Study setting

People suffering from chronic pain in Norway are generally followed up by primary health care including general practitioners and physiotherapists. However, in many regions including Bergen there is limited availability of treatment and follow-up, especially when an interpreter is needed. Similarly, people suffering from mental health suffering are generally followed up by primary health care and/or tertiary health care including general practitioners and psychologists (generally with need for referral). However, in many regions including Bergen there is limited availability of follow-up by psychologists, and specific cultural competence is scarce.

Participants and recruitment

We recruit adult Syrian refugees (age ≥ 16 years) living in Bergen and adjacent municipalities from several arenas: educational activities in which the newly arrived immigrants initially are enrolled in groups of approximately 30 students;

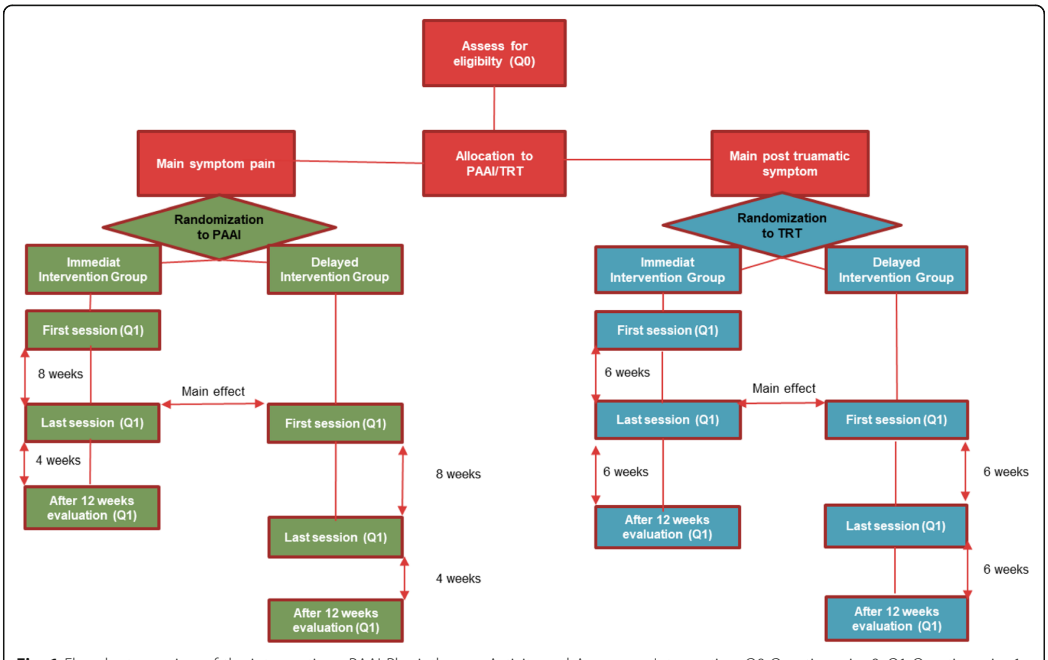

Fig. 1 Flowchart overview of the interventions. PAAI Physiotherapy Activity and Awareness Intervention, Q0 Questionnaire 0, Q1 Questionnaire 1, TRT Teaching Recovery Techniques

	STUDY PERIOD									
	Enrolment	Allocation		Post-allocation						Close-out
TIMEPOINT	*$-t_1$*	*0*	*T_1 (1^{st} week)*	*T_6 (6^{th} week)*	*T_{D1} (7^{th} week)*	*T_8 (8^{th} week)*	*T_{D1} (9^{th} week)*	*T_{D6} (12th week)*	*T_{D8} (16th week)*	*tx*
ENROLMENT:										
Invitation to persons with pain symptoms and posttraumatic symptoms	X									
Filling out Q0	X									
Allocation PAAI		X								
Allocation TRT		X								
INTERVENTIONS:										
Immediate Intervention TRT			X	X						After 12 weeks
Immediate Intervention PAAI			X			X				After 12 weeks
Delayed Intervention TRT					X			X		After 12 weeks
Delayed Intervention PAAI							X		X	After 12 weeks
ASSESSMENTS:		Q0	Q1for TRT& PAAI	Q1 for TRT	Q1 for TRT	Q1 for PAAI	Q1 for PAAI	Q1 for TRT	Q1 for PAAI	Q1

Fig. 2 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) schedule of enrolment, interventions and assessments. PAAI Physiotherapy Activity and Awareness Intervention, Q0 Questionnaire 0, Q1 Questionnaire 1, TD delayed intervention (same intervention at a later time point), TRT Teaching Recovery Techniques

patients from health care providers both in primary and secondary care and pharmacies, especially from areas with a high number of immigrants; and other non-health related locations where refugees often gather, like specific immigrant shops (e.g. Middle-Eastern and Asian grocery stores). In these settings, adults from Syria are shortly informed about the study in Arabic by the first author, who speaks Arabic and Norwegian. Adults with either pain or post-traumatic symptoms who are willing to participate are given an individual appointment for further information and potential inclusion. At this point, those consenting fill out the baseline questionnaire (Q0 — see Additional file 1). This questionnaire is used to identify participants fulfilling the inclusion criteria regarding pain and/or post-traumatic symptoms. All participants are invited to contact the first author for more information at any point of the study.

Inclusion criteria

Participants have to report either pain or post-traumatic symptoms in order to be included in one of the two interventions. Patients with physical pain are included if they report chronic pain that has lasted more than 6 months and score 3 or higher for either of the two items about pain severity on the Brief Pain Inventory (BPI) short questionnaire assessing average and current pain ranging from 0 to 10 [25]. Patients who answer yes to the question "Have you experienced any of these or some other terrifying event(s)?" and score over 24 on the revised Impact of Events Scale (R-IES) are included. The IES-R yields a total score ranging from 0 to 88 [26]. Patients scoring 20 or more on the General Health Questionnaire-12 (GHQ-12) are referred to a consultation with one of our collaborating psychologists in Bergen municipality before invitation to group participation, to make sure that he or she can benefit from group participation. If group participation is considered unfitting, the patient is referred to individual treatment.

Participants are allocated to either the PAAI or the TRT intervention according to their symptoms. Participants who present both pain complaints and post-

traumatic symptoms in whom symptom scores measured as a relative percentage of the maximum respective scales, BPI and IES-R, are highest are invited to the intervention treatment.

Exclusion criteria

Potential participants are excluded if they report health conditions requiring close medical follow-up, like diabetes with complications or cancer under treatment, or score on the mental health questions as having a serious mental illness (25 or more on the GHQ-12) and are assessed by psychologists to need individualized therapy. These patients will be referred to the appropriate level of care. Practical situations that impede attendance to treatment on a regular basis, like living far away from the therapy locations, are also a reason for exclusion.

Allocation and blinding

A random allocation sequence was generated by a statistician using the ralloc command in Stata version 15. The sequence was obtained using a 1:1 allocation ratio in block randomization with block sizes varying between 4, 6 and 8. Separate randomization sequences were made for the PAAI and TRT. After generation of the lists, each line was numbered from 1 upward, reflecting the order of recruitment (participation number). Participants were individually randomized. To be able to recruit within periods that are shorter than the time delay between intervention and delayed list groups (6–8 weeks), and in order to be able to provide interventions of adequate size, recruitment is organized in three waves followed by three rounds of interventions.

It will not be possible to blind the participants or the instructors in this study during the active intervention phase. The person who recruits participants and assigns participation numbers does not have access to the randomization list. Unfortunately, this person (WH) is both recruiting and assessing outcomes and we only have one statistician, so further blinding is not possible.

Interventions

In collaboration with Bergen municipality, the Centre for Crisis Psychology and the users, two interventions were developed and adapted to our population.

Physiotherapy Activity and Awareness Intervention (PAAI)

The physiotherapy treatment is based on principles from Norwegian psychomotor physiotherapy and general physiotherapy exercises and is led by physiotherapists working at Bergen municipality. In order to ensure the follow-up and guiding of each person, and to be able to handle reactions that might occur, 10–12 persons are invited into each group. Interpreters are oriented on their role in the group as well as the exercises. The words and phrases the therapists will use for instruction are shared with the interpreters beforehand, as there might be variants of Arabic depending on the country background of the interpreters. The intervention consists of eight sessions lasting approximately 1 h each with the same key elements each time: an introduction with welcome ball game and mindfulness exercises; sitting on the chair with a number of movements; lying down and relaxation; standing proprioceptive exercise; active movements stimulating balance, coordination and breathing; and, finally, grounding and short closing round.

The instructors explain the therapy and advise the participants to pay attention to their own limitations, for example, regarding pain and range of motion. Each participant is encouraged to do as much as possible of the exercises, within her or his capability at the beginning of each session. Otherwise, any injuries will be reported in the study and followed by the physiotherapists within the regular health care system.

Teaching Recovery Techniques (TRT)

TRT is designed in a step-by-step practical way to develop skills and techniques helpful in coping with the psychological effects of serious traumatization. In our case, the manual is adjusted for adults, with relevant examples and homework. All health professionals and collaborating interpreters involved in this intervention have previously been trained on the TRT manual by the Centre for Crisis Intervention. TRT is scheduled to one session weekly for 6 weeks; one session lasts approximately 2.5 h with up to 15 participants. The sessions deal with intrusive thoughts and feelings, arousal and avoidance in this order. To avoid secondary exposure and traumatization, participants are not required to disclose examples from their own life during group meetings, but they are asked to bring back memories of what happened to them. Participants will have tasks that are considered safe to carry out as homework.

User involvement in development of the interventions

Representatives from the Syrian population in Bergen participated in a consulting group and contributed to the development of the interventions in May–June 2018. Eight persons from Syria, including both women and men, with different backgrounds and positions in society, were recruited and asked for their general opinion of the interventions regarding various subjects. These included: the need for gender-segregated or age-segregated groups; the frequency, the most appropriate time of the day and day of the week to conduct group sessions; the importance of socializing; the need to coordinate childcare during the sessions; the necessity of reminders (by SMS) prior to each session; giving recommendations on appropriate clothing for the sessions; preferences for

interpreters; and so on. We will try to follow this advice as much as possible, including separate groups for women and men, in the implementation of the interventions.

Sample size calculation

For calculation of statistical power, we assumed that differences at baseline will be random for the immediate intervention and delayed intervention groups. We calculated the necessary sample size using an independent-sample *t* test with 80% power and a significance level of 5%. We used mean and standard deviation values based on earlier findings by our research group among 150 refugees from Syria in Lebanon waiting to be sent to Norway (not yet published).

For the PAAI, we assumed a mean of 6.0 and SD of 3.8 in the BPI "normal" pain scale (range 0–10) and considered as clinically significant a difference of 3 points on the given scale. These calculations gave a minimum size of 27 participants in each of the immediate and delayed PAAI groups. Assuming 25% attrition, the numbers needed are 34 participants in each of the study arms; this is to say, a total of 68 participants are needed for the PAAI. Since each PAAI group will have approximately 10–12 participants, we will need 3–4 immediate intervention groups and 3–4 delayed intervention groups for the PAAI. Similarly, for the TRT intervention we assumed a mean of 35.6 points and SD of 15, 5 on the IES-R scale (range 0–80) and 13.1 points in change as clinically significant (and SD of 0.75). These calculations gave a study size of 30 participants for the immediate and delayed TRT groups. We allowed a 30% dropout for this type of intervention, giving 39 participants per study arm. Thus, 78 participants are needed for TRT. Since each group will have approximately 10–12 participants, we will need 3–4 immediate intervention groups and a similar number of delayed intervention groups for the TRT intervention.

Measurements

Under the guidance of a bilingual field worker, two self-completed questionnaires in Arabic will be used. The more comprehensive baseline questionnaire (Q0) is used for the identification of participants as already described. A follow-up questionnaire (Q1 — see Additional file 2) will be used at the first and last sessions of the interventions as well as 12 weeks after the first session. The same questionnaires will be used for both interventions, TRT and the PAAI. The questionnaires have three parts covering: socioeconomic and migration-related information, which is more extensive in Q0; well-being and sense of coherence; and health status and health habits.

The questionnaires include instruments already translated and validated in Arabic as part of the CHART (Changing health and health care needs along the Syrian refugees' trajectories to Norway) study [27], including the sociodemographic questions. The Well-Being Index WHO (Five) and the 13-item Sense of Coherence Scale (SOC-13) [28, 29] are used in the second part of the questionnaire. For the assessment of physical and mental health in the third part, health-related risk factors and use of non-prescribed medication, validated questions from The Nord-Trøndelag Health Study (HUNT 3) are used [30]. For the assessment pain, the Brief Pain Inventory (BPI) — Short Form is used [25]. To assess individual distress caused by traumatic events, the Impact of Events Scale — Revised (IES-R 22) is used [26]. The General Health Questionnaire (GHQ-12) is used to identify non-psychotic and minor psychiatric disorders in the general population and is sensitive to short-term psychiatric disorders [31].

Systematic qualitative observation following a pre-structured scheme (Additional file 3) will be conducted by a bilingual researcher (PhD candidate) sitting in the room during the intervention and taking detailed notes regarding when and how the intervention is introduced and conducted, the questions being asked, any actions taken by the team leaders to implement the effect of the interventions in situ and how participants interact with each other and with the team leader during the training session. Each group will be observed at least three times (1 h for PAAI sessions and 2.5 h for TRT sessions) with the aim of capturing changes and processes after consent from the members of the group.

To further understand the mechanisms of action and participants' experiences as well as investigating the fit with the broader context of care delivery, we will interview participants from each group after the intervention is finished. The interviews will be recorded and transcribed verbatim. No personal data will be linked with the recorded material. Questions used will be adapted from those used by Sarkadi et al. [23] in Sweden in their evaluation of a group intervention for unaccompanied refugee minors with symptoms of PTSD.

Outcomes

The study has two main outcome measures: pain will be measured through mean scores assessed by the BPI, with a range from 0 to 10 (the cutoff point is set as scores ≥ 3); post-traumatic symptoms will be measured through the IES-R, with a range from 0 to 88. Mean scores will be calculated. Treatment effects will be measured by comparing the differences in main outcomes assessed from the post-intervention questionnaire in the immediate group compared to the pre-intervention questionnaire in the delayed list group. As secondary outcomes, psychological disorders will be assessed through the GHQ-12 with a range from 0 to 36, for which mean

scores will be calculated and differences between the immediate and delayed interventions groups adjusting for pain/IESR score at baseline will be assessed.

Analysis and statistical methods

Baseline characteristics will be presented separately for the two groups within each of the two trial arms (PAAI and TRT), with medians and interquartile range for continuous variables and counts and percentages for categorical variables. All data will be analyzed according to the intention-to-treat principle. All tests will be two-sided and 5% will be used as the level of significance. The trial will follow the CONSORT guidelines for publication of results.

The immediate effect of the interventions will be assessed by comparing the scores of the immediate intervention participants at the last treatment session (6 or 8 weeks for TRT and the PAAI, respectively) with the scores of the delayed intervention participants right after they begin their intervention. This will mean a 1-week delay in the measurements of both groups. The effect after 6/8 weeks will be assessed using linear regression, with the continuous measure of the outcome at 6/8 weeks (BPI, IESR) as the dependent variable and the allocation group as the independent variable with adjustment for baseline score of the outcome. The effect will be reported as regression coefficients with 95% confidence intervals and can be interpreted as the mean difference in scores after 6/8 weeks between the immediate intervention and the delayed intervention groups after adjustment for potential differences in outcome at baseline. Because group dynamics and other aspects of group membership could cause correlations between individuals within groups, we will calculate intraclass correlation coefficients for the outcomes and apply mixed-effects linear regression with random intercept and slope for group membership. Missing data will be considered, and appropriate multiple imputations based on characteristics measured at baseline will be done when necessary. As all participants will receive the intervention, additional cohort analyses will be conducted to supplement evaluation of the duration of the effect of the interventions.

Potential harms

There is a potential risk of worsening mental or pain symptoms through the interventions, and the leaders of the groups are trained to identify and treat or refer patients that present signs of worsening during the meetings. If substantial worsening is found among the participants at the last assessment in either mental or pain symptoms, individual interventions will be recommended based on advice from involved clinicians. The interpreter will be present for 30 min after each session so that there is time to debrief and deal with what happened in the group that day. This is beneficial both for safeguarding the participants and also for the interpreters, who also often have a refugee background and might be affected by the happenings in the group. There are no provisions for post-trial care other than those included in the regular health system. Norway has a patient insurance schema, which could be relevant for compensation if the participants are harmed by participation.

Data management and monitoring

The core study team for the CHART study (Health and health care needs among Syrian refugees), of which this RTC is a part (https://www.uib.no/en/generalpractice/chart), is composed by the principal investigator of the study, three other senior researchers and three PhD students, one of them with the main responsibility for this part of the study. Indeed, coordination is a main issue in the implementation of a RCT with two arms like ours. The core study team and Bergen municipality will have regular meetings to check the overall progress of the interventions, ensure adherence to the protocol, quality of the study and ethical conduct. In addition, the Centre for Crisis Psychology has certified all health professionals and collaborating interpreters involved in the TRT intervention, and has regular contact with the municipality and the university to ensure fidelity to their intervention. Interpreters working for the PAAI will attend a course to learn the special language/terminology used during the PAAI in advance.

The University of Bergen is responsible for collecting and plotting the data. Double data entry will be conducted, and data will be stored on a secure data server. Data cleaning with range checks for data values will be conducted before analysis.

Although we have an external reference group for the CHART study composed of national and international stakeholders, including user representatives, there will not be an independent auditing or data monitoring committee.

Discussion

In this study, we will develop and test two interventions to treat common symptoms among Syrian refugees in Norway: pain and post-traumatic symptoms. We have chosen to develop group-based interventions in collaboration with the users and the health care providers who usually deliver the services. This involves accommodating their suggestions when it comes to delivery, aiming to produce treatment options that are feasible and scalable to the rest of the refugee population if proven safe and effective. Our research project will improve the knowledge on the impact of group physiotherapy and

TRT among refugees from Syria with pain disorders or post-traumatic symptoms, and this evidence will be probably applicable to other groups of refugees with minimal adaptation.

The design of the study has some limitations and several strengths. The study is individually randomized, minimizing potential confounding. The study size should be sufficient to answer the primary objectives with reasonable precision; however, recruiting refugees has previously been difficult for other studies. We have therefore invested time and effort to establish a relationship with the community based on trust, mutual benefit and feedback and have involved users from the beginning. The study includes several researchers with refugee background themselves and builds upon a main study in which recruitment has been successful [27]. However, as the trial is not blinded, this could introduce information bias or the Hawthorne effect but at the same time contributes to improved external validity [32]. Ideally, we should have used a full factorial design to be able to estimate the effect of TRT on pain, the effect of the PAAI on mental health symptoms and a possible interaction effect between TRT and the PAAI, but this would require a much larger sample size for both trials and the numbers of Syrian refugees with pain or mental health symptoms in Bergen would not be enough. Comorbidity between mental health problems and pain disorder is common. The PAAI is expected to also have some effect on mental health problems in addition to its assumed main effect on pain reduction, and TRT is also expected to have some effect on pain in addition to its assumed main effect on trauma symptom reduction. Using one intervention as a control for the other would therefore not be adequate. Denying participants access to treatment when diagnosed with symptoms would be unethical, therefore we opted for a delayed intervention. Thus, we chose an immediate versus delayed intervention study design for both interventions. The study is funded from public sources, ensuring independence.

Trial status

The study was registered at Clinical Trials.gov on 19 February 2019 (ID: NCT03951909). Enrolment started in July 2018 and was completed in September 2019.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s13063-019-3919-x.

Additional file 1. Baseline Questionnaire Q0.

Additional file 2. Follow-up Questionnaire Q1.

Additional file 3. Embedded process evaluation.

Additional file 4. Informed consent form.

Additional file 5. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents.

Abbreviations

BPI: Brief Pain Inventory; GHQ: General Health Questionnaire; HUNT 3: The Nord-Trøndelag Health Study; IESR: Impact Event Scale — Revised; PAAI: Physiotherapy Activity and Awareness Intervention; PTSD: Post-traumatic stress disorders; Q0: Questionnaire 0; Q1: Questionnaire 1; SD: Standard deviation Assigned to TRT; SOC-13: Sense of Coherence Scale-13; TRT: Teaching Recovery Techniques; WHO (Five): Well-Being Index-5

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Authors' contributions

ED is the principal investigator, designed the study and obtained the funding. WH participated in the design of the interventions, conducted the interviews with the consultant group, started recruitment, prepared the first draft of the paper, including the figures, and has coordinated the feedback of all other authors. JI coordinated the statistical design. LTF, EMS, JH-Y, BNK, RV, LMG and UH participated in the design of the interventions and contributed to the writing process. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets that will be generated and/or analyzed during the current study will not be publicly available due to confidentiality of sensitive data, but are available from the corresponding author on reasonable request and following the Norwegian ethical norms. The data will be analyzed and published in peer-reviewed journals by the study group. Authorship will follow Vancouver rules.

Ethics approval and consent to participate

The study was approved by the regional ethical committee on 20 June 2018 (REK 2018/603). The trial will be conducted in strict accordance with the Declaration of Helsinki and with Good Clinical Practice (GCP) standards [33]. Any changes in the protocol will be reported to the regional ethical committee (REK West), following ordinary procedures in Norway [34]. Written informed consent will be obtained from each participant in their own language (Additional file 4). Handling of biological specimens is not applicable to this trial.

Consent for publication

This manuscript does not contain any individual person's data in any form. All authors have consented for publication.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

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Article

The Effect of Physiotherapy Group Intervention in Reducing Pain Disorders and Mental Health Symptoms among Syrian Refugees: A Randomized Controlled Trial

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Abstract: Chronic pain is common among refugees, and often related to mental health problems. Its management, however, is often challenging. A randomized waitlist-controlled trial was designed to study the effect of group physiotherapy activity and awareness intervention (PAAI) on reducing pain disorders, and secondarily improving mental health, among Syrian refugees. A total of 101 adult Syrian refugees suffering from chronic pain were randomized to either the intervention group or the control group, which thereafter also received PAAI after a waiting period. Pain intensity measured by the Brief Pain Inventory (BPI) was the primary outcome. Scores from the Impact of Events Scale-Revised (IES-R 22) and the General Health Questionnaire (GHQ-12) were secondary outcomes. Intention-to-treat analyses (ITT) showed no effect of the intervention on either pain levels (regression coefficient [B {95% CI} of 0.03 {−0.91, 0.96}], IESR scores [4.8 {−3.7, 13.4}] or GHQ-12 scores [−0.4 {−3.1, 2.3}]). Yet, participants highly appreciated the intervention. Despite the negative findings, our study contributes to the evidence base necessary to plan targeted and effective health care services for refugees suffering from chronic pain and highlights the challenge of evaluating complex interventions adapted to a specific group.

Keywords: group intervention; pain; mental health; Syrian refugees; randomized controlled trial

1. Introduction

Armed conflicts and war often result in displacement and mass migrations. More than one million Syrians reached the European Union in 2015 [1], becoming the largest refugee group in many European countries, including Norway [2,3].

Refugees are at high risk of developing chronic pain [4–6]. The reported prevalence of chronic pain among Syrian refugees varies between 30% in Norway [7] and 37% in Australia [8]. Physical limitations, such as walking difficulties, are described for 47% of Syrian refugees in Lebanon [9].

However, chronic pain is understudied in this group, and the literature often focuses primarily on mental health, especially post-traumatic stress disorder (PTSD) [10]. Indeed, poor mental health and chronic pain reinforce each other [11]. Chronic pain can disturb daily functioning, which can lead to mental distress [12,13], and mental health problems can have a negative impact on the experience of pain [14].

In 2015, a study from Norway reported that the prevalence of chronic pain among those attending an outpatient mental health clinic was 66% in the host population versus 88% among traumatized refugees [4]. Similar findings are reported from Denmark, the United Kingdom, and Germany [14–16]. In other comorbidity studies, the prevalence of PTSD among persons with chronic pain ranges from 10% to 50%, while the prevalence of chronic pain among persons with PTSD ranges from 20% to 80% [17,18].

The understanding and management of chronic pain is influenced by tradition and culture [19]. When arriving in the host country, refugees should be offered appropriate and culturally acceptable forms of health care. In the Nordic countries, combinations of basic body awareness therapy (BBAT) and general physiotherapy exercises integrating Eastern and Western traditions have been used as treatment [20–22]. BBAT is reported to have a positive impact among patients with chronic pain and mental health symptoms [20,23,24]. Psychomotor physiotherapy was developed in Norway and focuses on increasing awareness of the body–mind relationship [25]. However, there is little evidence of the effect of physiotherapy on refugees in either pain or mental health symptoms.

While individual treatment allows for personalized therapy, group dynamics might be preferred by refugees, who often lack social contact with peers upon arrival in the new country [26,27]. A recent systematic review and meta-analysis found that group and individual physiotherapy delivered similar results and that group programs may need to be considered more often [28]. However, there is a lack of evidence of the effect of group physiotherapy versus individual physical activity, as part of the treatment for chronic pain among refugees [29,30].

The University of Bergen (Norway), in collaboration with the Center for Migration Health at the municipality of Bergen, developed a new group physiotherapy activity and awareness intervention (PAAI) based on previous clinical experience with group interventions for refugees [31] and influenced by principles found in BBAT and psychomotor physiotherapy. We hypothesize that PAAI conducted in groups would ineffectively help reduce pain disorders among Syrian refugees and also improve mental health. The aim of this study was to evaluate this effect, as, and also participants' experiences of the intervention.

2. Materials and Methods

2.1. Study Design

This RCT is part of the main study 'Changing health and Health care Needs Along the Syrian refugee's Trajectories to Norway '(CHART). The trial was registered with Clinical Trials.gov on https://clinicaltrials.gov/ct2/show/NCT03951909. To include user participation in the design of the interventions, the study was retrospectively registered on 19 February 2019. The regional ethics committee approved the study in June 2018 (REK 2018/603), and informed written consent was given by all the participants.

The protocol of the intervention studies in CHART has been previously described following the SPIRIT recommendations [31]. CHART includes two randomized waitlist-controlled trials, one testing a self-help group intervention for mental health symptoms, not described in this paper, and the other, reported here, testing a physiotherapy activity and awareness intervention. Given the prevalent coexistence of chronic pain and mental health problems among refugees, participants with pain symptoms and/or mental health problems were recruited between 2018 and 2019 for both trials at the same time. As described in the protocol, participants with the greatest burden of pain symptoms were allocated to the PAAI intervention and randomized to either an immediate intervention group or a

delayed intervention group, which received the same intervention but at a later point in time for ethical reasons. For the rest of the paper, we refer to the groups as intervention and control despite the fact that the last group also received the intervention after the evaluation of the main results. Details regarding sample size calculations have previously been described (31). An initial sample size of 34 participants in each group was calculated to be able to detect an intervention effect of 3 points on the BPI pain intensity scale participants with 80% power and a significant level of 5% and assuming 25% attrition.

2.2. Participants

As reported in the protocol [31], Syrian refugees 16 years or older living in Bergen and adjacent municipalities, with pain symptoms and/or mental health problems, were informed about the study in Arabic by the first author at different arenas. Those who consented to participate filled out a baseline questionnaire (Q0) in Arabic, under the guidance of a bilingual field worker. Among the 180 recruited, 101 had predominant burden of pain symptoms compared to mental health symptoms and were included in the PAAI trial reported in this paper. Of these, 50 participants were randomized to the intervention group and 51 to the control group. A total of 29 participants withdrew after randomization before initiation of the interventions. Thirty-eight participants (76%) from the intervention group and 34 (67%) from the control group attended the first session and completed the questionnaire the day the group sessions began (Q1a). Thirty-one participants (62%) from the intervention group and 24 (47%) from the control group completed the same questionnaire (Q1b) eight weeks after the group sessions ended. Twenty-seven participants (54%) from the intervention group and 23 (47%) from the control groups answered the questionnaire (Q1c) 12 weeks after the group sessions ended. Figure 1 shows the CONSORT flow chart. The number of participants who attended the PAAI sessions in both groups are summarized, by gender, in Supplementary Table S1.

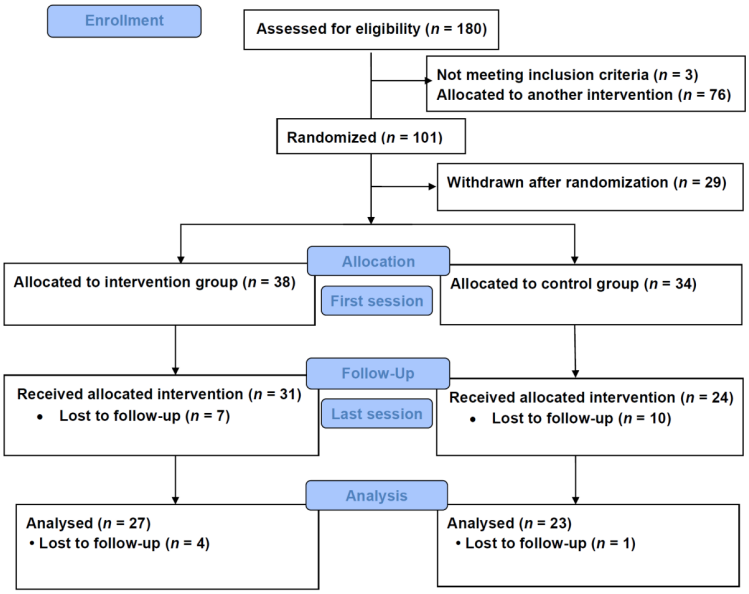

Figure 1. CONSORT flow chart.

2.3. Inclusion and Exclusion Criteria

Participants who reported pain symptoms that lasted over six months and scored 3 or higher in any of the average or current pain severity scores of the BPI were eligible for inclusion. Participants who lived far away from the therapy locations were excluded from the study. Those who scored 25 or

higher on the GHQ-12 or 37 or higher on the IES-R 22 were assessed by a psychologist prior to their involvement in the study to decide the suitability of group treatment, since high scores could indicate serious mental health problems. The requirement of close medical follow-up (e.g., for those receiving treatment for diabetes with complications or for cancer) was also considered as exclusionary criterion, although no participant was excluded for these reasons.

2.4. Intervention

As explained in detail in the protocol, eight Syrians of both genders and not related to the study were consulted, on the practical implementation of PAAI, specifically with regard to the gender issues and session timing [31]. Physiotherapists with previous experience working with refugees led the PAAI sessions weekly for 8 weeks in groups of up to 10 persons. Each session lasted an hour and included the same key elements each time: mindfulness exercises and ball games warm-ups, followed by exercises involving sitting on a chair, laying down, relaxation, coordination and breathing exercises, and a short closing round [31]. The sessions were held in Norwegian with an Arabic interpreter, separately for women and men, and by a therapist and an interpreter of the same gender as the group. Instructions, phrases, and particular words used by therapists were shared with interpreters prior to the sessions. Participants were advised to pay attention to their own limitation regarding pain and range of motion, and were actively invited to comment on their own feelings during or after the sessions and report to the physiotherapists any injury or worsening of pain related to the sessions.

In order to assess whether the intervention met with the initial plan and to monitor activity in the groups, the first author conducted systematic observation, taking detailed notes following a predesigned protocol (Appendix A, Figure A1) during the sessions, at least twice in each group. The therapists kept the agreed plan as described in the protocol. The only difference noticed in the dynamic of the groups was related to gender. In the female groups, all were active, curious, interested, expressed satisfaction, acted friendly towards each other, and seemed to have fun. The male groups were less active, with some participants seeming less satisfied and not networking as much with each other. The interpreter's Arabic dialect was not necessarily Syrian on every occasion, but there were no signs of misunderstandings.

2.5. Outcomes

The primary outcome was the degree of pain measured by the pain intensity domain of BPI, calculated as the mean of the four items on pain intensity (range 1–10). The secondary outcomes were scores from the IES-R 22 and GHQ-12 questionnaires [31]. All outcomes were measured right after the intervention in the intervention group and right before the start of the delayed intervention in the control group. The same outcomes were used for the additional longitudinal analyses of change during the intervention phase for both groups combined.

2.6. Measures

Two similar questionnaires, Q0 and Q1, were translated into Arabic and developed, as explained in the protocol [31]. Both included questions on socio-demographics and migration, and health status, including chronic pain and mental health. Q0 was longer and used to identify participants at baseline. Q1 was shorter and was applied three times: at the beginning of the intervention (Q1a), after eight weeks, i.e., at the end of the intervention (Q1b), and 12 weeks after the first session of the intervention, i.e., four weeks after the intervention ended (Q1c).

Pain in the last six months was measured using the four pain severity items (worst pain, least pain, average pain, pain right now) included in the BPI—Short Form (BPI-SF). Each of the items can be scored from 0 to 10 [31]. The IES-R 22 and the GHQ-12 were used to assess mental health. IES-R 22 measures the subjective response to a specific traumatic event in adult populations, especially with respect to intrusion, avoidance, and hyper-arousal. The three areas together provide a total subjective stress IES-R score (range 0–88). IES-R is not a diagnostic tool. The GHQ-12 scale is developed for

the general population, as opposed to patients, asking whether the respondent has experienced a particular symptom or behavior recently. It includes 12 items, each of which is rated on a 4-point scale (less than usual, no more than usual, rather more than usual, or much more than usual), giving a maximum total score of 36 (range 0–36). Both instruments have been validated among Arabic-speaking refugees [32,33].

Additionally, to gain an insight into experiences with the intervention, we conducted a simple qualitative explorative study with a phenomenological design. After the group interventions, individual semi-structured interviews were conducted in Arabic by the first author (Figure A2). Questions in these interviews where adapted from Sarkadi et al., in their evaluation of a group intervention for unaccompanied refugee minors [34]. In total, 17 interviews were conducted, 11 with participants who had fulfilled the intervention and six with participants who dropped out before or during the sessions, from both the intervention and the control (delayed intervention) groups.

2.7. Randomization and Blinding

A block randomization was conducted using a 1:1 allocation ratio, with block sizes of 4, 6, and 8 generated by a statistician using the rollac command in Stata software, version 15. To provide interventions in suitable time, recruitment was planned in three waves, followed by three rounds of interventions. The time difference in starting the intervention between the intervention and control groups was eight weeks. The intervention was not blinded, neither for the participants, nor for the instructors or authors. The first author recruited the participants and assessed outcomes but did not have access to the randomization list.

2.8. Statistical Analysis

Baseline characteristics are presented for the intervention and control groups by means and standard deviations for continuous variables and counts and percentages for categorical variables. The intention-to-treat (ITT) principle was used. The effect of the intervention on the primary outcome was assessed using linear mixed models with random intercept for individuals and the BPI pain intensity score as a dependent variable (Equation (1)). Data were analyzed in long format (two observations per individual), with the BPI score at Q0 as the first BPI measurement for each individual. The second measurement was defined as the measurement at the last treatment session (eight weeks) in the intervention group and the measurement at the first session for the control group. The following constrained linear mixed model was estimated:

$$BPI_i = \beta\_0 + \beta\_1 \cdot TIME + \beta\_2 \cdot TIME \cdot GROUP + b\_0_i + \varepsilon \quad (1)$$

where TIME is a binary variable (0/1) with Q0 (time of randomization) as the reference, GROUP is a binary group allocation variable with the control group as the reference, and $b0_i$ is the random intercept for each individual i. The intervention effect was estimated as the interaction effect between GROUP and TIME. By omitting the main effect of group from the model, we achieved an adjustment for baseline differences in BPI [35]. Corresponding models were estimated for the secondary outcomes IES-R and GHQ and also for BPI pain interference as a supplementary off-protocol outcome. The intervention effect was reported as regression coefficients for the interaction term with 95% confidence intervals and can be interpreted as the mean difference in change in outcome score after eight weeks between the intervention and control groups after adjustment for potential differences in outcome at baseline. In line with the ITT principle, we included all 101 individuals who were randomized in the model. All individuals had baseline measurements (Q0), but in total, 36 participants were lost to follow-up and had missing values on the second measurement. The approach with linear mixed model data in long format provides unbiased estimates of the intervention effect as long as follow-up data are missing at random, given the covariates included in the model. As a sensitivity analysis, we repeated the linear mixed models with adjustment for variables that were significantly different between participants with

complete data and participants who were lost to follow-up. As a second sensitivity analysis, we also applied mixed effects linear regression with random intercept and slope for group membership to investigate if differences in group dynamics within each recruiting wave could influence the results.

In longitudinal analyses of changes during the intervention phase and the four weeks after the last session for the intervention and control (delayed intervention) groups combined, we used data in long format with three observations per person and applied linear mixed effects regression with random intercept for each individual. Inclusion of the random slope for time did not improve model fit and we therefore only estimated the fixed effect for time. Time was modelled both as a categorical covariate with the first session as the reference and as a continuous covariate with the values 0, 8, and 12 in order to test for a linear trend over weeks. Differences in change over time between genders were investigated by stratification and by inclusion of an interaction-term between time and gender.

Stata SE version 16 was used to analyze the data. All tests were two-sided, with a 5% level of significance.

2.9. Qualitative Analysis

The interviews were recorded and transcribed. Two Arabic speakers translated the interviews from Arabic to English, which were then sent to a professional translator with the original records for quality assurance. A master student (EZN) coded and analyzed the interviews in close collaboration with supervisors. No specific analysis software was used. Systematic text condensation was then used in the analysis, which consisted of four steps: (1) achieving a total impression—from chaos to themes; (2) identifying and sorting meaning units—from themes to codes; (3) condensation—from code to meaning; and (4) synthesizing—from condensation to descriptions and concepts, as described by Malterud [36,37]. Only the main themes are presented here for the sake of parsimony.

3. Results

The baseline characteristics of the participants randomized to intervention and control groups (n = 101) are presented in Table 1. Participants in both groups were similar in most respects but were younger in the control group, and a higher percentage was married and had children in the intervention group. We found no differences in either BPI scores, IES-R 22 or GHQ-12, between the two groups at baseline. The groups were also balanced in terms of exposure to stressful events, self-reported health, and daily use of medication. From the 101 randomized participants, 65 had follow-up data on the main and secondary outcomes (31 in the intervention and 34 in the control groups). A comparison of baseline characteristics between the 65 participants with 2 measurements and the 36 participants with only baseline measurement is reported in Supplementary Materials Table S2. The lost-to-follow-up less had stayed in a transit country before migrating to Norway, were more physically active, and had higher education but were otherwise similar to the actual participants.

Table 2 shows the ITT effect of the intervention on chronic pain (BPI) and mental health scores (IES-R 22 and GHQ-12), based on the scores at baseline and after treatment for the intervention group and at baseline and at the end of the waiting period for the control group. Intra-cluster correlation coefficients for correlation of repeated measures within individuals were 0.66, 0.61, and 0.68 for BPI, IES-R 22, and GHQ-12, respectively. The ITT analyses comparing the intervention against the control groups after adjustment for baseline BPI measurement showed no effect of the intervention on pain levels, with a regression coefficient (95% CI) of 0.03 (−0.91, 0.96). With regard to mental health, IESR scores increased non-significantly in the intervention group by 4.8 points, and did not change in the control group, and there was no significant effect of the intervention. GHQ-12 scores were reduced by 1.4 and 0.8 points in the intervention and control groups, respectively, but the intervention effect was not significant, with a regression coefficient (95% CI) of −0.4 (−3.1, 2.3). In the supplementary analysis of the pain interference inventory of the BPI, change in both the intervention and control groups was not significant, with regression coefficients (95% CI) of −0.67 (−1.52, 0.18) and 0.40 (−0.21, 1.01),

respectively. The effect of the intervention was in the direction of increased pain interference but was not significant, with a regression coefficient (95% CI) of 0.97 (−0.17, 2.12).

As additional analyses, Figure 2 shows the longitudinal change in the mean levels of BPI, IES-R 22, and GHQ-12 separately for men and women and for all participants together (n = 101) taking into account the intervention period for the control group, after having waited for the treatment. For BPI and GHQ-12, there was a significant reduction from the first session (week 0) until the last session (week 8) for both men and women, and the measurement in week 12 was also significantly reduced compared to week 0, as summarized in Supplementary Materials Table S3. The test for linear change with week treated as a continuous covariate was significant in both men and women for BPI and GHQ-12. The reduction was somewhat larger in women compared to men, but the test for interaction between gender and week was not significant (p = 0.69 for BPI and p = 0.85 for GHQ). For IES-R, there were no significant changes over time in either men or women.

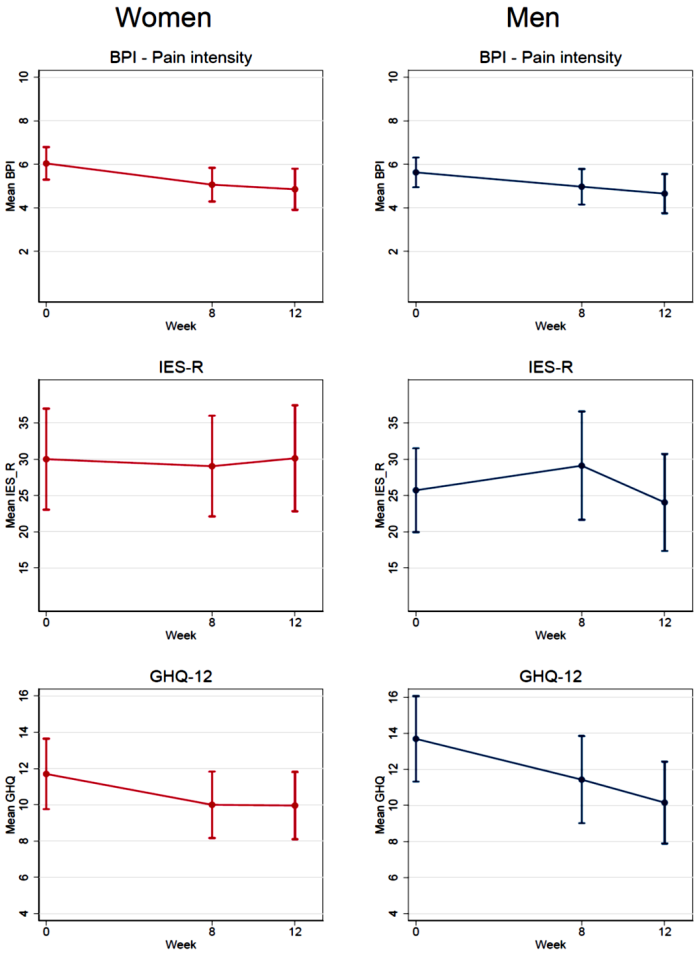

Figure 2. Levels of BPI (pain intensity), IES-R, and GHQ-12 for all participants at different intervals. Note: Week 0 = first PAAI session, week 8= last PAAI session and week 12 = four weeks after last session. Interventions and controls (after participating in the intervention -waitig list-) are presented together, stratified by gender. Mean scores with 95% confidence intervals.

Table 1. Characteristics of the intervention and control groups at baseline.

		Intervention Group	Control Group
Total		50	51
Age (years), Mean (SD)		39 (11)	34 (11)
Low health literacy, *n* (%)		28 (56)	22 (43)
Female, *n* (%)		19 (38)	21 (41)
Ethnicity, *n* (%)	Arab	42 (84)	35 (69)
	Kurd	8 (16)	15 (29)
Stayed in any transit country on the way to Norway, *n* (%)		27 (54)	33 (65)
Marital status (married), *n* (%)		35 (70)	27 (53)
Have children, *n* (%)		39 (78)	29 (57)
Number of children, Mean (SD)		3 (1.4)	3 (1.4)
Education (years), Mean (SD)		9 (4.5)	9 (4.1)
Self-reported health, *n* (%)			
	Poor	21 (42)	20 (39)
	Neither	20 (40)	19 (37)
	Good	9 (18)	12 (24)
Self-reported diseases and daily use of medication, *n* (%)			
Physical or psychological pain at least 1 year		33 (66)	27 (53)
Physical pain more than6 months		36 (72)	39 (76)
Never do exercise		26 (52)	23 (45)
Rheumatic arthritis		9 (18)	10 (20)
Joint disease		33 (66)	38 (75)
Mental health problems		5 (10)	8 (16)
Headache		16 (32)	13 (25)
Daily use of painkillers		15 (30)	12 (24)
Daily use of psychotropics		3 (6)	7 (14)
Study outcomes			
IES-R, Mean (SD)	Intrusion (8–32)	9 (7.5)	9 (7.8)
	Avoidance (8–32)	9 (8.4)	10 (7.4)
	Hyper-arousal (6–24)	7 (5.8)	7 (5.9)
IES-R scores ≥37, *n* (%)		15 (30)	18 (35)
BPI scores	Having pain today (yes), *n* (%)	50 (100)	50 (98)
	Pain intensity (1–10), Mean (SD)	5.8 (1.9)	5.8 (2.3)
	Pain interference (1–10), Mean (SD)	4.4 (2.5)	4.5 (2.4)
GHQ-12 (0–36), Mean (SD)		12.7 (6.7)	12.5 (6.1)
GHQ-12 scores ≥25, *n* (%)		2 (4)	1 (2)

Table 2. Effect of PAAI intervention on the primary and secondary outcomes. Intention to treat analyses using linear mixed models.

The Primary and Secondary Outcomes	Intervention, $n = 50$			Control, $n = 51$			Intervention Effect	
	Baseline (Q0). Mean (SD)	Last Session (Q1b). Mean (SD)	*p*-Value *	Baseline (Q0). Mean (SD)	End of Waiting Period (Q1a). Mean (SD)	*p*-Value *	B (95% CI)	*p*-Value
BPI	5.8 (1.9)	5.5 (2.1)	0.14	5.8 (2.3)	5.5 (2.1)	0.07	0.03 (−0.91, 0.96)	0.95
IES-R	25.9 (20.0)	31.2 (15.8)	0.10	26.7 (19.6)	25.8 (19.3)	0.90	4.8 (−3.7, 13.4)	0.27
GHQ-12	12.7 (6.7)	11.4 (6.1)	0.03	12.5 (6.1)	11.7 (5.3)	0.05	−0.4 (−3.1, 2.3)	0.76

Note: * Paired t-test for within-group change; PAAI = Physiotherapy activity and awareness intervention.

Participants' Reflections on the Intervention

The qualitative analyses revealed three main themes. First, the participants greatly appreciated the sessions as a meeting place or social support platform for their community to gather and talk about the common challenges of being newcomers to Norway. Second, the intervention equipped the participants with tools to apply in everyday life, like learning to focus on the body, which in turn led to better sleep, healthy seating, and including particular movements in their daily routine. These elements enhanced self-confidence and gave the participants a feeling of control over their own health. Third, the participants described the facilitators (e.g., good therapist, good interpreter, positive environment, the possibility of breaking everyday routines, etc.) and barriers (e.g., session timings that clashed with family duties or medical appointments, especially for women, or dissatisfied gossipers) to their participation in the intervention.

4. Discussion

Our study focuses on chronic pain among refugees, adding new important information to the research that has previously focused mostly on mental health problems. To the best of our knowledge, this is the first trial to study the effects of physiotherapy group intervention among refugees with chronic pain. From an ITT point of view, our physiotherapy group intervention (PAAI) had no effect on reducing either pain disorders or improving mental health in our sample of refugees. However, the participants were satisfied with the intervention, and reported that it had provided them with the tools to apply in everyday life.

When comparing our study with previous research, we found only one pragmatic trial recently conducted among traumatized refugees with PTSD in Denmark in which participants were randomized to receive either individual BBAT or two other types of individualized therapy. This study showed no significant difference in improvement between groups in the ITT analysis, but a small significant improvement in the longitudinal analysis [38], which is similar to our study. This might be explained because PAAI did not specifically target either trauma or mental health. While other interventions directly targeting traumatic experiences like eye movement desensitization and reprocessing (EMDR) and emotional freedom techniques (EFTs) are effective for the treatment of trauma [39], they might not help with chronic pain, which was our main outcome. Our trial found no clear overall effects of the intervention itself in pain reduction after 8 and 12 weeks. There are several potential explanations for this. It is possible that the intervention was not sufficiently adapted for the participants and their situations. We found that 52% of the intervention group, and 45% of the control group said they never exercised. This is a difficult barrier to overcome and might necessitate a different kind of intervention. A third of the participants did not even attend the first meeting, and the qualitative interviews indicate that participating in the intervention could to some degree come into conflict with other activities and could contribute some degree of stress to an already busy life. Compared to the lost-to-follow-up, the participants had a longer migrating path to Norway, were less physically active, and had lower education, and it is also possible that the participant selection process involved a high proportion

of treatment-resistant participants who might have tried and failed different treatments and were therefore difficult to help. Although we used validated tools to measure pain, pain can fluctuate, and we might have selected participants at a time when they had a very high degree of symptoms. In that case, any later measure will be more likely to be lower, in what is known as regression to the mean.

Among the Syrian refugees participating in this RCT, 68% were exposed to stressful events. All presented pain, it was an inclusion criterion, and most reported some degree of mental health symptoms. However, only 12% reported high levels of mental health problems. Previous RCT studies using physiotherapy among refugees have mainly focused on the effect it has on mental health symptoms like PTSD, major depression, anxiety, and stress [23,40–43]. These studies showed little effect of the treatment on these mental disorders. In the longitudinal analyses, our results seem to point to a differential effect of PAAI on mental health depending on the questionnaire used. While there was no effect or even worsening in scores for IES-R, the results were more positive for GHQ-12, used for the general population and not specifically for patients with mental health problems. This might indicate that PAAI could be better suited to improving mental health among persons with milder mental health symptoms. However, we did not have the power to stratify the analyses according to symptoms. More research into this field should be conducted, as mild mental health symptoms are very prevalent among refugees.

In two previous studies, the effect of BBAT among general psychiatric patients in Sweden, and among traumatized refugees in Denmark did not differ by gender [21,43]. This is in line with our study where no gender differences were found in the longitudinal analyses despite the slight difference in dynamics observed in both female and male groups.

Even if our intervention did not have an effect, there was statistically significant improvement in both groups with time, which might be due to factors other than the intervention or because of the Hawthorne effect where participants have a desire to please researchers. However, the results of our semi-structured interviews show that the group sessions were positive for the participants in several ways, including social and instrumental. Especially interesting are the qualitative results pointing to improvement in sleep quality, reduction of stress, and increase in self-confidence, which might decrease pain levels [40]. This improvement was also seen in a Swedish study using basic body awareness intervention [40,44], and should be further studied.

Our study has some important strengths. First, our trial was successful in terms of balance between the intervention and control groups. We managed to include the number of participants necessary to be able to find an effect in a group that is considered difficult to reach, since we had counted on a 30% drop out of participants based on physiotherapists' previous experience. Related to this, the Arabic background of resource persons in the project, coupled with meetings with interpreters to discuss vocabulary beforehand, reduced language barriers. Second, the complementary use of both qualitative and quantitative methods to understand the effect of the intervention gives us a deeper understanding necessary for the implementation of future interventions in the real world [45]. Additionally, the close monitoring by observation of the sessions enabled us to understand the differences in dynamics between groups, depending on gender, that could be further investigated by statistical analyses. Lastly, there was close and well-established cooperation between the different organizations and municipalities in Norway, which facilitated recruitment of participants and implementation of the intervention. In collaboration with the municipality of Bergen, we chose to only include refugees from Syria, the largest migrant group in Norway since 2015, as including a range of groups could have complicated language translation in the sessions. However, we believe our study could also be generalized for other refugee populations suffering from chronic pain.

Our study has also limitations, including the relatively short intervention period and the limited length of the sessions, lasting only one hour each, which may have been insufficient. The delayed intervention design, judged as the only ethically acceptable solution, also made it difficult to assess potentially delayed effects that might exhibit at a later stage but were not present immediately after the intervention. In addition, outcome measures in our study were self-reported, and neither the participants, the outcome assessors, nor those conducting data analysis were blinded. However, we did our best to quality check the process in all its parts. Even though we had a consultant group to help us adapt the intervention to the lives of the participants, mandatory educational activities for newly resettled Syrian refugees, and issues related to childcare were the main reasons for participants dropping out from the session. This had an impact on attendance at the PAAI sessions, which was relatively low, reducing the power in our analyses and eventually introducing a potential selection bias. A low attendance rate, even lower than ours, is common in this type of study [38,42]. To overcome these limitations, future studies should try to tailor interventions to refugees' lives even more and should ensure longer intervention periods.

5. Conclusions

Our study shows no effect of PAAI on either chronic pain or mental health symptoms among Syrian refugees living in Norway. However, participants were satisfied with the intervention and reported other beneficial effects and no side effects.

Our study contributes to the evidence base necessary to plan targeted and effective health care services for a vulnerable group and at the same time highlights the challenge of evaluating complex interventions adapted to a specific group.

Supplementary Materials: The following are available online at http://www.mdpi.com/1660-4601/17/24/9468/s1, Table S1: Number of participants who attended physiotherapy activity and awareness intervention (PAAI) sessions in each intervention and control group, by gender. Table S2: Group comparisons on characteristics of follow-up and dropout. Table S3: Change in outcomes from first to last sessions and four weeks after last session for intervention and control groups combined (n = 101) using liners mixed models.

Author Contributions: Conceptualization E.D., B.K.; methodology W.H., E.D., B.K., E.Z.N., and J.I., L.T.F.; formal analysis J.I., W.H., L.T.F. and E.D.; writing—original draft preparation W.H.; writing—review and editing W.H., J.H.-Y., E.M.S., E.Z.N., R.V., J.I., L.T.F., B.K. and E.D.; supervision E.D., B.K., and L.T.F. All authors have read and agreed to the published version of the manuscript.

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Appendix A

Evaluation scheme to be used in interventions (3 times / per group)

Reminder to the group that the researcher is only there to note and not to interpret or answer questions while the group is in progress. Try to be as "invisible" as possible in the room.

1- How is the intervention presented / implemented?

Interpreter: Present? Sex? Dialect?

Questions from participants to the leader of the group — what is asked? Note specific questions (not need answers)

Misunderstandings?

Do instructors change any part of the intervention? If something, what?

Participants' body language? E.g. mainly sitting in open or "closed" positions (hands in cross etc. subject to cultural differences)

Are participants? (Give examples)

o All active alike?

o Passive?

o Asking many questions?

o Satisfied?

o Encouraged by instructors to activity?

o Participants contact the instructors via another participant

2- How do participants interact? (Nice, social, laughter, tense, supportive)

3- Language (Arabic, Kurdish, Norwegian)

4- Heterogeneity and homogeneity in the group: Are there similarities and/or differences between group members: clothing, roles etc.

5- Other relevant points noticed.

Interpreter:

Instructor:

Group:

Date:

Figure A1. Embedded Process Evaluation.

1. How was it to be contacted by SMS?
2. How was it like to participate in the group?
3. What has been important for you in the group sessions?
4. Would you have liked more/less of something in the group?
5. Did you feel that any of the exercises were not relevant for you?
   If so which?
6. Did you feel that any of the exercises were difficult to carry out for you? If so, which?
7. Which exercise did you feel was the most helpful?
8. Did you get injuries or other negative consequences due to your participation in the group sessions?
9. Did you feel comfortable in the group? Explain, what made you feel this way?
10. Can you tell me about the relationships in the group?
11. Have you made some new friends within the group?
12. Have you met with group members outside the group sessions that you did not know before?
13. Would you recommend the group to someone your age? Why or why not? What would you say to others?
14. Anything else you want to tell us.

Figure A2. Questions That Will Be Used for Evaluation of PAAI Group Interventions (Sarkadi et al. Sweden).

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Paper III

Supplementary files (1-12)

1. Informed consent form-questionnaire used at base line and at the beginning of the interventions (in English, available in Arabic upon request)
2. Informed consent form-personal interview (in English, available in Arabic upon request)
3. Poster placed on the doors and entrances of schools, shops and waiting rooms of practices of medical clinics (in English, available in Norwegian and Arabic upon request)
4. Letter send to general practitioners, physiotherapists, and psychologists (in English, available in Norwegian upon request)
5. SMS send to all Syrian participants who went to school (in English, available in Arabic upon request)
6. Letter to the director of the school (in English, available in Norwegian upon request)
7. Pre-structured scheme used to take notes on when and how the interventions were implemented and carried out
8. Table: Number of interviews for participants by gender and duration of interview
9. Table: PAAI sensitivity analyses: group comparisons on characteristics of follow-up and dropped out
10. Table: Change in outcomes in PAAI intervention from first to last sessions and four weeks after last session
11. Table: TRT sensitivity analyses: group comparisons on characteristics of follow-up and dropped out
12. Table: Change in outcomes in TRT intervention from first to last sessions and four weeks after last session

Informed consent form-questionnaire

'Effect of physiotherapy and psychological group treatment on physical and mental health among refugees from Syria with pain disorders or post-traumatic symptoms"

Background information:

The University of Bergen together with the municipalities of Bergen are conducting a study about the effect of two interventions on the health of Syrian refugees and asylum seekers to Norway. The results from the study will increase our knowledge about the health of refugees in Norway and will help us to provide better health care services. This is an invitation for you to participate in this study by answering a questionnaire survey.

Participant selection:

All 16 years or older persons from Syria with pain disorders of post-traumatic stress symtoms are invited to participate in this study by answering a self-administered anonymous questionnaire. The questionnaire takes 20-25 minutes to complete, and includes general demographic questions, questions related to health, well-being, health status and health habits.

Confidentiality:

We will register your name and personal identification in information in the questionnaire only as long as you are part of the study and in order to contact you for the interventions. All personal information will be deleted after the study. Information about you that will be collected through the questionnaire will be kept confidential and stored safely. Only the researchers will have access to your information, which will only be used in accordance with the purpose of the study as described above. This study is not linked to any other legal institution and cannot affect your eventual permission or denial to stay in the country.

Rights to refuse or withdraw:

Participating in the Syrian Refugee Health Survey is your choice. You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your regular health exam or treatment in any way. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. If you have any questions about this survey, please talk to the person who gave you the questionnaire.

Consent for participation in the study:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I know that I may refuse to participate or to stop at any time without any loss of health care benefits that I am otherwise receiving.

Date

Respondent Signature

Interviewer Signature

Informed consent form-personal interview

'Effect of physiotherapy and psychological group treatment on physical and mental health among refugees from Syria with pain disorders or post-traumatic symptoms"

Background information:

The University of Bergen together with the municipality of Bergen studying the health and health care services offered to Syrian refugees and asylum seekers to Norway. The results from the study will increase our knowledge about the health of refugees in Norway and will help us to provide better health care services. This is an invitation for you to participate in this study by being interviewed about this theme.

Participant selection:

Selected adults that have taken part in the interventions are invited to a personal interview to share their experiences of the treatment received in the study. The interview takes 30-45 minutes and aims to better understand your experiences regarding the treatment sessions you have gone through.

Confidentiality:

We will not register your name or personal identification number or other directly recognisable type of information. Information you share will be recorded and transcribed and kept confidential and stored safely. Only the researchers will have access to your information, which will only be used in accordance with the purpose of the study as described above. This study is not linked to any other legal institution and cannot affect your eventual permission to stay in the country.

Rights to refuse or withdraw:

Participating in the Syrian Refugee Health Survey is your choice. You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your regular health exam or treatment in any way. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here.

Consent for participation in the study:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked to have been answered to my satisfaction. I consent voluntarily to be interviewed. I know that I may refuse to participate or to stop at any time without any loss of health care benefits that I am otherwise receiving.

Date

Respondent Signature

Interviewer Signature

CHART

Are you from Syria and you are over 16 years old?

Do you have persistent pain in your body (for example in the neck, back and joints)?

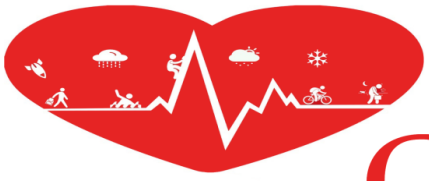
Do you often feel sad, suffer from anxiety or feel unhappy?

The University of Bergen together with the Centre for Migration Health in Bergen municipality offers you free treatment from August

For more information, please contact

Phone number: 90239341 (Arabic) from July 16, 2018

Or send a message to e-mail: wegdan.hasha@uib.no



CHART

Dear GP / physiotherapist

Do you have patients from Syria who have chronic pain or mental illness?

The University of Bergen in collaboration with the Center for Crisis Psychology and Bergen Municipality (SEMI) is now recruiting patients over the age of 16 for a project that offers free group treatment.

 For patients with mental disorders, we offer psychoeducation in groups of 2 hours per week over 5 weeks.

 For patients with chronic pain, we offer physiotherapy that emphasizes awareness of the body and physical activity in groups of one hour weekly over 8 weeks.

 The groups start at the end of august, but will continue throughout the year!

Get in touch if you have patients who may be relevant.
Patients can also contact the undersigned directly for information in Arabic (09-19: 00)
Mobile No. 90239341+ WhatsApp
Email. Wegdan.hasha@uib.no

With best regards!
Wegdan Hasha, PhD student
Esperanza Díaz, Associate Professor
Department of Global Public Health and Primary Care, University of Bergen

Hi

A few months ago, we called several adults from Syria to tell us what their health was like. We thank everyone who participated.

Now we have the results and inviting everyone from Syria (including those who did not attend) to a meeting where we talk about:

What is the health situation among Syrians in Bergen?

Do they have a lot of diseases?

Are they satisfied with health care?

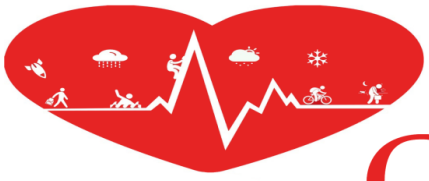
Is there anything they can do to improve health?

At the meeting, we will also inform you of the free treatment offer for those who are in pain in the body or are often sad, anxious, or feeling unhappy.

Please come to the meeting .....

For more information, please call: 90239341 (Arabic)

Or send an email to: wegdan.hasha@uib.no



CHART

Dear integration consultant / teacher

Do you have participants / students from Syria who have chronic pain or mental illness?

We are now recruiting patients over the age of 16 for a project that offers free group treatment in collaboration with Bergen Municipality (SEMI).

 For patients with mental disorders, we offer psychoeducation in groups of 2 hours per week over 6 weeks. The treatment plan has been developed in collaboration with the Center for Crisis Psychology and Bergen Municipality.

 For patients with chronic pain, we offer physiotherapy that emphasizes awareness of the body and physical activity in groups of one hour weekly over 8 weeks. The treatment plan has been developed in collaboration with the Center for Migration Health in Bergen municipality.

 The groups start in august, but will continue throughout the year!

keep in touch if you have participants / students who may be relevant.
Patients can also contact the author directly for information in Arabic (09-19: 00)

Wegdan Hasha, PhD student, Department of Global Public Health and Primary Care
Mobil nr. 90239341+ WhatsApp
Epost. Wegdan.hasha@uib.no

Embedded process evaluation

Evaluation scheme to be used in interventions (3 times / per group)

Reminder to the group that the researcher is only there to note and not to interpret or answer questions while the group is in progress. Try to be as "invisible" as possible in the room.

1- How is the intervention presented / implemented?

- Interpreter: Present? Sex? Dialect?
- Questions from participants to the leader of the group — what is asked? Note specific questions (not need answers)
- Misunderstandings?
- Do instructors change any part of the intervention? If something, what?
- Participants' body language? E.g. mainly sitting in open or "closed" positions (hands in cross etc. subject to cultural differences)
- Are participants? (Give examples)
    - All active alike?
    - Passive?
    - Asking many questions?
    - Satisfied?
    - Encouraged by instructors to activity?
    - Participants contact the instructors via another participant

2- How do participants interact? (Nice, social, laughter, tense, supportive)

3- Language (Arabic, Kurdish, Norwegian)

4- Heterogeneity and homogeneity in the group: Are there similarities and/or differences between group members: clothing, roles etc.

5- Other relevant points noticed.

Interpreter:

Instructor:

Group:

Date:

	INTERVENTION GROUP PAAI	CONTROL GROUP PAAI	INTERVENTION GROUP TRT	CONTROL GROUP TRT	DURATION OF INTERVIEW (MIN)	MALE	FEMALE
1	✓				16	X	
2	✓				18		X
3		X			19	X	
4		X			3		X
5		✓			9	X	
6		✓			15		X
7	✓				7		X
8	✓				12	X	
9	X				3	X	
10		X			3	X	
11		✓			19		X
12		✓			7	X	
13	X				1	X	
14	X				1		X
15	✓				6	X	
16	✓				5		X
17		✓			4		X
18			✓		41	X	
19			✓		40		X
20				✓	14	X	
21				✓	12	X	
22				✓	19		X
23				X	4	X	
24			X		4		X
25			✓		9	X	
26				✓	12	X	
27			✓		10		X
28				X	3		X
29				X	6	X	
30			X		3	X	
31			X		2	X	
32			✓		8		X
33				X	2		X
34			✓		5	X	
35				X	1		X
36				X	1	X	
37				✓	11	X	
38				✓	11	X	

Supplementery Table: *Number of interviews for participants by gender and duration of interview. Note:* ***X*** *= participants who dropped out,* ✓ *= participants who completed the intervention, PAAI= physiotherapy activity awareness intervention, TRT=teaching recovery techniques.*

		Follow-up	Dropout	P-value
Total		65	36	
Age (years), Mean (SD)		37.8 (10.3)	34.0 (12.8)	0.10
Low health literacy, N (%)		36 (55)	14 (39)	0.11
Female, N (%)		28 (43)	12 (33)	0.33
Ethnicity, N (%)	Arab	48 (74)	29 (81)	0.61
	Kurd	16 (25)	7 (19)	
Stayed in a transit country on way to Norway N (%)		46 (71)	14 (39)	0.002
Marital status (married), N (%)		42 (65)	20 (56)	0.37
Have children, N (%)		48 (74)	20 (56)	0.06
Number of children, Mean (SD)		3.4 (1.5)	3.2 (1.3)	0.55
Education (years), Mean (SD)		8.6 (4.2)	11.4 (3.9)	0.002
Self-reported health, N (%)				0.15
	Poor	31(48)	10(28)	
	Neither	22 (34)	17 (47)	
	Good	1218	9 (25)	
Self-reported diseases and daily use of medication, N (%)				
Physical or psychological pain at least 1year		41 (63)	19 (53)	0.31
Physical pain more >6 months		50 (77)	25 (70)	0.41
Never do exercise		38 (58)	11 (31)	0.007
Rheumatic arthritis		13 (20)	6 (17)	0.68
Joint disease		48 (74)	23 (64)	0.29
Mental health problems		8 (12)	5 (14)	0.82
Headache		22 (34)	7 (19)	0.12
Daily use of painkillers		19 (29)	8 (22)	0.73
Daily use of psychotropics		8 (12)	2 (6)	0.09
Exposure to stressful events		44 (68)	24 (67)	0.91
Study outcomes				
Impact events scales revised IESR, Mean (SD)	Intrusion (8-32)	9.4 (7.6)	9.3 (7.9)	0.96
	Avoidance (8-32)	9.5 (7.9)	10.7 (7.9)	0.46
	Hyper-arousal (6-24)	7.4 (5.7)	7 (5.8)	0.74
BPI scores	Having pain today (yes), N (%)	65 (100)	35 (97)	0.17
	Pain intensity (1-10), Mean (SD)	6.0 (1.9)	5.4 (2.3)	0.21
GHQ-12 (0-36), Mean (SD)		13.4 (6.1)	11.2 (6.7)	0.10

Supplementary Table. Group comparisons on characteristics of follow-up and dropped out

Supplementary Table. Change in outcomes PAAI from first to last sessions and four weeks after last session for intervention and control groups combined (n=101) using liners mixed models

		Week 0	Week 8		Week 12		P-trend
			B (85% CI)	p-value	B (85% CI)	p-value	
Total							
BPI		0 (ref)	-0.8 (-1.2, -0.5)	<0.001	-1.0 (-1.4, -0.6)	<0.001	<0.001
IES-R		0 (ref)	0.6 (-2.5, 3.7)	0.71	-0.5 (-3.7, 2.8)	0.78	0.90
GHQ		0 (ref)	-2.1 (-3.3, -0.9)	<0.001	-2.3 (-3.6, -1.1)	<0.001	<0.001
Women							
BPI		0 (ref)	-1.0 (-1.6, -0.5)	<0.001	-1.1 (-1.7, -0.5)	<0.001	<0.001
IES-R		0 (ref)	-2.8 (-6.8, 1.2)	0.17	-2.3 (-6.5, 1.9)	0.28	0.20
GHQ		0 (ref)	-2.0 (-3.6, -0.4)	0.02	-1.9 (-3.6, -0.2)	0.03	0.01
Men							
BPI		0 (ref)	-0.7 (-1.2, -0.2)	0.008	-0.9 (-1.4, -0.4)	0.001	<0.001
IES-R		0 (ref)	3.6 (-0.9, 8.2)	0.12	0.9 (-3.7, 5.6)	0.70	0.44
GHQ		0 (ref)	-2.1 (-3.8, -0.3)	0.02	-2.6 (-4.4, -0.8)	0.005	0.002

Note: P-valued for interaction tests by gender: BPI: 0.69, IES-R: 0.13 and GHQ: 0.85.

		Follow-up	Dropped out	P-value
Total		51	25	
Age (years), Mean (SD)		34.0 (10.3)	29.0 (10.1)	0.05
Low health literacy, N (%)		22 (43)	14 (56)	0.29
Female, N (%)		17 (33)	11 (44)	0.36
Ethnicity, N (%)	Arab	36 (71)	15 (60)	0.35
	Kurd	15 (29)	10 (40)	
Stayed in a transit country on way to Norway, N (%)		38 (75)	11 (44)	0.009
Marital statutus (married), N (%)		32 (63)	11 (44)	0.12
Have children, N (%)		30 (59)	11 (44)	0.22
Number of children, Mean (SD)		2.0 (2.0)	1.0 (1.7)	0.09
Education (years), Mean (SD)		9.8 (4.6)	10.6 (4.6)	0.45
Exposure to stressful events, N (%)		51 (100)	25 (100)	
Self-reported health, N (%)	Very poor	5 (10)	2 (8)	0.65
	Poor	11 (22)	2 (8)	
	Neither	18 (35)	11 (22)	
	Good	15 (29)	9 (36)	
	Very good	2 (4)	1 (4)	
Self-reported diseases and daily use of medication, N (%)				
Physical or psychological pain at least 1year		23 (45)	10 (40)	0.67
Physical pain more >6 months		27 (53)	5 (20)	0.006
Never do exercise		28 (55)	12 (48)	0.57
Rheumatic arthritis		5 (10)	3 (12)	0.76
Joint disease		16 (31)	6 (24)	0.50
Mental health problems		18 (35)	7 (28)	0.52
Headache		20 (39)	7 (28)	0.33
Daily use of painkillers		6 (12)	3 (12)	0.77
Daily use of psychotropics		1 (2)	3 (12)	0.09
Study outcomes				
Impact events scales revised IESR (0-88), Mean (SD)	Intrusion (8-32)	17.0 (6.3)	16.0 (5.6)	0.46
	Avoidance (8-32)	19.0 (4.9)	17.7 (5.5)	0.31
	Hyper-arousal (6-24)	13.0 (4.9)	11.0 (4.2)	0.12
BPI scores	Having pain today (yes), N (%)	43 (84)	18 (72)	0.20
	Pain intensity (4-40), Mean (SD)	23.9 (7.7)	21.7 (9.4)	0.13
	Pain interference (7-70), Mean(SD)	33.6 (16.0)	27.3 (17.8)	0.02
GHQ-12 (0-36)		16.7 (7.4)	14.7 (5.1)	0.22

Supplementary Table. Group comparisons on characteristics of follow-up and dropped out

Change in outcomes of TRT from first to last session and six weeks after last session for intervention and control groups combined (n=76) using linear mixed models.

		Week 0	Week 6	Week 12	P-trend
			B (95% CI)	B (95% CI)	
Total					
IES-R		0 (ref)	-6.0 (-10.2, -1.9)	-10.7 (-14.8, -6.6)	<0.001
GHQ		0 (ref)	-2.9 (-4.8, -1.0)	-3.3 (-5.2, -1.5)	<0.001
BPI		0 (ref)	-0.1 (-0.7, 0.5)	-0.6 (-1.2, 0.0)	0.059
Women					
IES-R		0 (ref)	-6.0 (-12.2, 0.3)	-6.5 (-12.4, -0.6)	0.032
GHQ		0 (ref)	-3.3 (-6.0, -0.5)	-1.8 (-4.4, 0.8)	0.185
BPI		0 (ref)	0.4 (-0.5, 1.2)	-0.1 (-0.9, 0.7)	0.846
Men					
IES-R		0 (ref)	-6.4 (-11.5, -1.2)	-13.0 (-18.3, -7.7)	<0.001
GHQ		0 (ref)	-2.8 (-5.2, -0.4)	-4.2 (-6.7, -1.7)	0.001
BPI		0 (ref)	-0.2 (-1.0, 0.5)	-0.8 (-1.6, -0.0)	0.043

P-valued for interaction tests by gender: IES-R: 0.27, GHQ: 0.35 and BPI: 0.41

Additional files (1-6)

1. CHART Questionnaire 0 used at baseline (in English, available in Arabic upon request)
2. CHART Questionnaire 1 used at the first and last sessions of the treatments and 12 weeks after the first session (in English, available in Arabic upon request)
3. Questions used for evaluation of PAAI group intervention
4. Questions used for evaluation of TRT group intervention
5. Ethical approval from the Regional Committee for Medical and Health Research Ethics of South East Norway (REC South East Norway)
6. Other publications related to the CHART project

Date:

Place:

Effect of physiotherapy and psychological group treatment on physical and mental health among refugees from Syria with pain disorders or post-traumatic symptoms

QUESTIONNAIRE Q0

Thank you for taking part in this study!

The information in this questionnaire will be used in research aimed to understand the effect of treatment in your health situation and to improve health care services for refugees. It is important that you answer all the questions. Please ask if there is something you do not understand. The completed questionnaire should be given back to the person who invited you to the study before you leave.

Please answer by putting an X in the box (☐), or answering the open fields ( ) as explained in the text.

By answering this questionnaire you accept that we use this information only for the purpose explained to you. All information will be treated in strict confidence.

Yours sincerely,
University of Bergen and Health Care services at the Municipality of Bergen.

FOR THE FIELD WORKER:

Has the participant already answered another questionnaire for this project (make sure that he/she knows which project you are talking about)? Has the person already participated in the Syria-health study?

No	Yes, in Bergen	Yes, in Kristiansand	Yes, in Lebanon	Yes, elsewhere
☐	☐	☐	☐	☐

HEALTH LITERACY SCREENING

1 **How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy in your own language?**

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

PART 1 – BACKGROUND INFORMATION

2 **Name:**

Please specify.

3 **Mobile phone number:**

Please specify (e.g. 123 45 678).

4 **Date of birth:** . . *(e.g. 01.06.1978)*

5 **Gender:** Woman ☐ Man ☐

6 **Which country were you born in?**

☐ Syria ☐ Iraq ☐ Other

Please specify (e.g. Turkey).

Survey number/ID:

7 What language is your native tongue?

☐ Arabic ☐ Kurmanji ☐ Sorani
☐ Armenian ☐ Other

Please specify (e.g. Turkish).

8 What is your ethnicity?

☐ Arab ☐ Kurd ☐ Armenian ☐ Other

Please specify (e.g. Turkish).

9 What is your marital status?

☐ Single ☐ Separated ☐ Married
☐ Divorced ☐ Widowed ☐ Cohabitant
☐ Other

10 If married, are you living with your partner(s)? Yes ☐ No ☐

11 Do you have children? Yes ☐ No ☐

12 How many children do you have?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 or more

13 How many years of education have you completed altogether? ☐☐ years
(e.g. 5 years)

14 What is your occupational status in Norway?

☐ Employed for wages (private or public)
☐ Self-employed ☐ Out of work
☐ Homemaker ☐ Student / introduksjonsprogrammet
☐ Retired ☐ Unable to work
☐ Other

Please explain.

15 When did you leave your home country?

Year: ☐☐☐☐ *(e.g. 2013)*

16 When did you arrive to Norway?

Month and year: ☐☐.☐☐☐☐
(e.g. 11.2013 for November 2013)

17 Did you arrive?

☐ Alone
☐ With all immediate family members
☐ With some immediate family members

18 Have you stayed in any transit country on the way to this place? Yes ☐ No ☐

19 If yes, in how many countries did you stay for more than a week?

☐ One ☐ Two ☐ Three ☐ More than three

20 If you have stayed in several countries on the way to this place, for how long (in total) did you stay in that country/ those countries?

☐ Up to 6 months ☐ 6-12 months
☐ 1-2 years ☐ More than two years

21 Were you ever retained against your will during the transit phase? Yes ☐ No ☐

22 What is your status in Norway now?

☐ Asylum seeker ☐ Refugee ☐ Other

PART 2 – WELL-BEING

23 Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3 in the upper right corner.

	All of the time					At no time
23.1 I have felt cheerful and in good spirits	5	4	3	2	1	0
23.2 I have felt calm and relaxed	5	4	3	2	1	0
23.3 I have felt active and vigorous	5	4	3	2	1	0
23.4 I woke up feeling fresh and rested	5	4	3	2	1	0
23.5 My daily life has been filled with things that interest me	5	4	3	2	1	0

Survey number/ID:

24 Here is a series of questions relating to various aspects of your life. Each question has seven possible answers. Please mark the number, which expresses your answer, with number 1 and 7 being the extreme answers. If the words under 1 are right for you, circle 1: if the words under 7 are right for you, circle 7. If you feel differently, circle the number which best expresses your feeling. Please give only one answer to each question.

	Very seldom or never						Very often
24.1 Do you have the feeling that you don't really care about what goes on around you?	1	2	3	4	5	6	7
	Never happened						Always happened
24.2 Has it happened in the past that you were surprised by the behaviour of people whom you thought you knew well?	1	2	3	4	5	6	7
	Never happened						Always happened
24.3 Has it happened that people whom you counted on disappointed you?	1	2	3	4	5	6	7
	No clear goals or purpose at all						Very clear goals and purpose
24.4 Until now your life has had:	1	2	3	4	5	6	7
	Very often						Very seldom or never
24.5 Do you have the feeling that you're being treated unfairly?	1	2	3	4	5	6	7
	Very often						Very seldom or never
24.6 Do you have the feeling that you are in an unfamiliar situation and don't know what to do?	1	2	3	4	5	6	7
	A source of deep pleasure and satisfaction						A source of pain and boredom
24.7 Doing the thing you do every day is:	1	2	3	4	5	6	7
	Very often						Very seldom or never
24.8 Do you have very mixed-up feelings and ideas?	1	2	3	4	5	6	7
	Very often						Very seldom or never
24.9 Does it happen that you have feelings inside you would rather not feel?	1	2	3	4	5	6	7
	Never						Very often
24.10 Many people – even those with a strong character – sometimes feel like sad sacks (losers) in certain situations. How often have you felt this way in the past?	1	2	3	4	5	6	7
	You overestimated or underestimated its importance						You saw things in the right proportion
24.11 When something happened, have you generally found that:	1	2	3	4	5	6	7
	Very often						Very seldom or never
24.12 How often do you have the feeling that there's little meaning in the things you do in your daily life?	1	2	3	4	5	6	7
	Very often						Very seldom
24.13 How often do you have feelings that you're not sure you can keep under control?	1	2	3	4	5	6	7

Survey number/ID:

PART 3 – HEALTH STATUS AND HEALTH HABITS

25 How do you consider your health at the moment?

Very poor ☐ Poor ☐ Neither ☐ Good ☐ Very good ☐

26 Have you had or do you have any of the following?
(Put an X on each line under No or Yes. If Yes, please explain.)

	No	Yes	Age first time	Not familiar
26.1 Heart attack/chest pain	☐	☐	26.2 ☐ years	☐
26.3 Heart failure	☐	☐	26.4 ☐ years	☐
26.5 Other heart disease	☐	☐	26.6 ☐ years	☐
26.7 Stroke/brain hemorrhage	☐	☐	26.8 ☐ years	☐
26.9 Kidney disease	☐	☐	26.10 ☐ years	☐
26.11 Liver disease	☐	☐	26.12 ☐ years	☐
26.13 Asthma	☐	☐	26.14 ☐ years	☐
26.15 Chronic bronchitis, emphysema or COPD	☐	☐	26.16 ☐ years	☐
26.17 Tuberculosis	☐	☐	26.18 ☐ years	☐
26.19 Diabetes	☐	☐	26.20 ☐ years	☐
26.21 Psoriasis	☐	☐	26.22 ☐ years	☐
26.23 Eczema on hands	☐	☐	26.24 ☐ years	☐
26.25 Cancer	☐	☐	26.26 ☐ years	☐
26.27 Arthritis *Rheumatoid arthritis*	☐	☐	26.28 ☐ years	☐
26.29 Other joint diseases	☐	☐	26.30 ☐ years	☐
26.31 Osteoporosis	☐	☐	26.32 ☐ years	☐
26.33 Fibromyalgia or generalized body pain	☐	☐	26.34 ☐ years	☐
26.35 Mental health problems you sought help for	☐	☐	26.36 ☐ years	☐
26.37 Epilepsy	☐	☐	26.38 ☐ years	☐
26.39 Headache	☐	☐	26.40 ☐ years	☐
26.41 Abdominal pain/diarrhoea	☐	☐	26.42 ☐ years	☐
26.43 Allergies	☐	☐	26.44 ☐ years	☐

27 Have you used any of the following medicines?
(Please place only one X for each medication at the answer that best fits your situation.)

	Daily	Weekly	Less than weekly	Never used
27.1 Drugs for peptic ulcer, gastro-esophageal reflux and digestion	☐	☐	☐	☐
27.2 Antithrombotics (aspirin, warfarin)	☐	☐	☐	☐
27.3 Cholesterol reducing medication	☐	☐	☐	☐
27.4 Medicine for high blood pressure	☐	☐	☐	☐
27.5 Medicine for diabetes mellitus	☐	☐	☐	☐
27.6 Medication for asthma or COPD	☐	☐	☐	☐
27.7 Painkillers, off prescription	☐	☐	☐	☐
27.8 Painkillers, on prescription	☐	☐	☐	☐
27.9 Sedatives	☐	☐	☐	☐
27.10 Tranquillizers	☐	☐	☐	☐
27.11 Anti-depressive medication	☐	☐	☐	☐
27.12 Medication for allergy	☐	☐	☐	☐
27.13 Other prescribed medication, but do not know for what	☐	☐	☐	☐

28 How often do you exercise?
(On average. Put an X in only one box)

☐ Never ☐ 2-3 times a week
☐ Less than once a week ☐ Nearly every day
☐ Once a week

29 About how many hours do you sit during a normal day?
(Both work hours and leisure time)

About ☐ hours *(e.g. 6 hours)*

30 Do you suffer from long-term (at least 1 year) illness or injury of a physical or psychological nature that impairs your daily life?

☐ Yes ☐ No

31 If yes, would you describe your impairment as slight, moderate or severe?

	Slight	Moderate	Severe
31.1 Motor ability impairment	☐	☐	☐
31.2 Vision impairment	☐	☐	☐
31.3 Hearing impairment	☐	☐	☐
31.4 Impairment due to physical illness	☐	☐	☐
31.5 Impairment due to mental health problems	☐	☐	☐

Survey number/ID:

32 **Do you have physical pain now that has lasted more than 6 months?** Yes ☐ No ☐

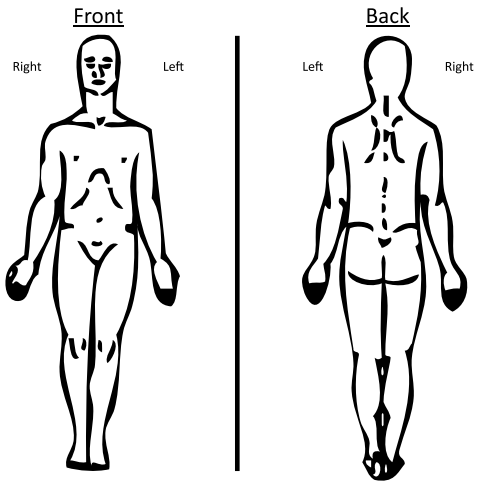
33 **If yes, how strong has your physical pain been during the last 4 weeks?**

No pain ☐ Very mild ☐ Mild ☐ Moderate ☐ Strong ☐ Very strong ☐

BRIEF PAIN INVENTORY (SHORT FORM)

34 **Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?** Yes ☐ No ☐

35 **On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.**



36 **Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.**

No pain									Pain as bad as you can imagine
1	2	3	4	5	6	7	8	9	10

37 **Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.**

No pain									Pain as bad as you can imagine
1	2	3	4	5	6	7	8	9	10

38 **Please rate your pain by marking the box beside the number that best describes your pain on the average.**

No pain									Pain as bad as you can imagine
1	2	3	4	5	6	7	8	9	10

39 **Please rate your pain by marking the box beside the number that tells how much pain you have right now.**

No pain									Pain as bad as you can imagine
1	2	3	4	5	6	7	8	9	10

40 **What treatments or medications are you receiving for your pain?**

Please specify.

41 **In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.**

No relief									Complete relief
10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

42 **Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:**

42.1 **General activity**

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

42.2 **Mood**

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

42.3 **Walking ability**

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

42.4 **Normal work**
(includes both work outside the home and housework)

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

42.5 **Relations with other people**

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

Survey number/ID:

42.6 Sleep

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

42.7 Enjoyment of life

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

43 Exposure to a stressful event or situation (either short or long lasting) of exceptionally threatening or catastrophic nature is likely to cause pervasive distress in almost anyone. Examples of such difficult and frightening experiences are: being assaulted, or witnessing other people being hurt or killed.

	Yes	No
Have you experienced any of these or some other terrifying event(s)?	☐	☐

IMPACT OF EVENTS SCALE - REVISED (IES-R)

INSTRUCTIONS: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you **during the past seven days** with respect to _____ (event) that occured on _____ (date). How much have you been distressed or bothered by these difficulties?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
44.1 Any reminder brought back feelings about it.	0	1	2	3	4
44.2 I had trouble staying asleep.	0	1	2	3	4
44.3 Other things kept making me think about it.	0	1	2	3	4
44.4 I felt irritable and angry.	0	1	2	3	4
44.5 I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	2	3	4
44.6 I thought about it when I didn't mean to.	0	1	2	3	4
44.7 I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
44.8 I stayed away from reminders of it.	0	1	2	3	4
44.9 Pictures about it popped into my mind.	0	1	2	3	4
44.10 I was jumpy and easily startled.	0	1	2	3	4
44.11 I tried not to think about it.	0	1	2	3	4
44.12 I was aware that I still had a lot of feelings about it but I didn't deal with them.	0	1	2	3	4
44.13 My feelings about it were kind of numb.	0	1	2	3	4
44.14 I found myself acting or feeling like I was back at that time.	0	1	2	3	4
44.15 I had trouble falling asleep.	0	1	2	3	4
44.16 I had waves of strong feelings about it.	0	1	2	3	4
44.17 I tried to remove it from my memory.	0	1	2	3	4
44.18 I had trouble concentrating.	0	1	2	3	4
44.19 Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
44.20 I had dreams about it.	0	1	2	3	4
44.21 I felt watchful and on-guard.	0	1	2	3	4
44.22 I tried not to talk about it.	0	1	2	3	4

Survey number/ID:

GHQ-12

45 **We would like to know how you have been feeling the last couple of months. Please mark the option that best suits your situation.**

During the last two weeks, have you:

25.1 Been able to concentrate on what you're doing?	Better than usual	As usual	Less than usual	A lot less than usual
25.2 Lost much sleep over worry?	Has not happened	Not more than usual	More than usual	I slept a lot less than usual
25.3 Felt that you are playing a useful part in things?	More than usual	As usual	Less than usual	A lot less than usual
25.4 Felt capable of making decisions about things?	More than usual	As usual	Less than usual	A lot less than usual
25.5 Felt constantly under strain?	Not at all	Not more than usual	More than usual	A lot more than usual
25.6 Felt you couldn't overcome your difficulties?	Not at all	Not more than usual	More than usual	A lot more than usual
25.7 Been able to enjoy your normal day to day activities?	More than usual	As usual	Less than usual	A lot less than usual
25.8 Been able to face up to your problems?	Better than usual	As usual	Less than usual	A lot less than usual
25.9 Been feeling unhappy or depressed?	Not at all	Not more than usual	More than usual	A lot more than usual
25.10 Been losing confidence in yourself?	Not at all	Not more than usual	More than usual	A lot more than usual
25.11 Been thinking of yourself as a worthless person?	Not at all	Not more than usual	More than usual	A lot more than usual
25.12 Been feeling reasonably happy for day-to-day activities?	More than usual	As usual	Less than usual	A lot less than usual

THANK YOU FOR ANSWERING THESE QUESTIONS! PLEASE MAKE SURE TO RETURN THIS FORM TO THE PERSON WHO GAVE IT TO YOU BEFORE LEAVING.

Date:

Place:

Effect of physiotherapy and psychological group treatment on physical and mental health among refugees from Syria with pain disorders or post-traumatic symptoms

QUESTIONNAIRE Q1

Thank you for taking part in this study!

The information in this questionnaire will be used in research aimed to understand the effect of treatment in your health situation and to improve health care services for refugees. It is important that you answer all the questions. Please ask if there is something you do not understand. The completed questionnaire should be given back to the person who invited you to the study before you leave.

Please answer by putting an X in the box (☐), or answering the open fields ( ) as explained in the text.

By answering this questionnaire you accept that we use this information only for the purpose explained to you. All information will be treated in strict confidence.

Yours sincerely,
University of Bergen and Health Care services at the Municipality of Bergen.

FOR THE FIELD WORKER:

Has the participant already answered another questionnaire for this project (make sure that he/she knows which project you are talking about)? Has the person already participated in the Syria-health study?

No	Yes, in Bergen	Yes, in Kristiansand	Yes, in Lebanon	Yes, elsewhere
☐	☐	☐	☐	☐

HEALTH LITERACY SCREENING

1 **How often do you need to have someone help you when you read instructions, pamphlets, or other written material from your doctor or pharmacy?**

Never	Rarely	Sometimes	Often	Always
☐	☐	☐	☐	☐

PART 1 – BACKGROUND INFORMATION

2 **Name:**

Please specify.

3 **Mobile phone number:**

Please specify (e.g. 123 45 678).

4 **Date of birth:** ☐☐.☐☐.☐☐☐☐ *(e.g. 01.06.1978)*

5 **What is your status in Norway now?**

☐ Asylum seeker ☐ Refugee ☐ Other

Survey number/ID:

PART 2 – WELL-BEING

6 Please indicate for each of the five statements which is closest to how you have been feeling over the last two weeks. Notice that higher numbers mean better well-being.

Example: If you have felt cheerful and in good spirits more than half of the time during the last two weeks, put a tick in the box with the number 3 in the upper right corner.

	All of the time					At no time
6.1 I have felt cheerful and in good spirits	5	4	3	2	1	0
6.2 I have felt calm and relaxed	5	4	3	2	1	0
6.3 I have felt active and vigorous	5	4	3	2	1	0
6.4 I woke up feeling fresh and rested	5	4	3	2	1	0
6.5 My daily life has been filled with things that interest me	5	4	3	2	1	0

7 Here is a series of questions relating to various aspects of your life. Each question has seven possible answers. Please mark the number, which expresses your answer, with number 1 and 7 being the extreme answers. If the words under 1 are right for you, circle 1: if the words under 7 are right for you, circle 7. If you feel differently, circle the number which best expresses your feeling. Please give only one answer to each question.

	Very seldom or never						Very often
7.1 Do you have the feeling that you don't really care about what goes on around you?	1	2	3	4	5	6	7
	Never happened						Always happened
7.2 Has it happened in the past that you were surprised by the behaviour of people whom you thought you knew well?	1	2	3	4	5	6	7
	Never happened						Always happened
7.3 Has it happened that people whom you counted on disappointed you?	1	2	3	4	5	6	7
	No clear goals or purpose at all						Very clear goals and purpose
7.4 Until now your life has had:	1	2	3	4	5	6	7
	Very often						Very seldom or never
7.5 Do you have the feeling that you're being treated unfairly?	1	2	3	4	5	6	7
	Very often						Very seldom or never
7.6 Do you have the feeling that you are in an unfamiliar situation and don't know what to do?	1	2	3	4	5	6	7
	A source of deep pleasure and satisfaction						A source of pain and boredom
7.7 Doing the thing you do every day is:	1	2	3	4	5	6	7
	Very often						Very seldom or never
7.8 Do you have very mixed-up feelings and ideas?	1	2	3	4	5	6	7
	Very often						Very seldom or never
7.9 Does it happen that you have feelings inside you would rather not feel?	1	2	3	4	5	6	7

Survey number/ID:

	Never						Very often
7.10 Many people – even those with a strong character – sometimes feel like sad sacks (losers) in certain situations. How often have you felt this way in the past?	1	2	3	4	5	6	7

	You overestimated or underestimated its importance						You saw things in the right proportion
7.11 When something happened, have you generally found that:	1	2	3	4	5	6	7

	Very often						Very seldom or never
7.12 How often do you have the feeling that there's little meaning in the things you do in your daily life?	1	2	3	4	5	6	7

	Very often						Very seldom
7.13 How often do you have feelings that you're not sure you can keep under control?	1	2	3	4	5	6	7

PART 3 – HEALTH STATUS AND HEALTH HABITS

8 How do you consider your health at the moment?

Very poor ☐ Poor ☐ Neither ☐ Good ☐ Very good ☐

9 Have you used any of the following medicines?
(Please place only one X for each medication at the answer that best fits your situation.)

	Daily	Weekly	Less than weekly	Never used
9.1 Painkillers, off prescription	☐	☐	☐	☐
9.2 Painkillers, on prescription	☐	☐	☐	☐
9.3 Sedatives	☐	☐	☐	☐
9.4 Tranquillizers	☐	☐	☐	☐
9.5 Anti-depressive medication	☐	☐	☐	☐
9.6 Other prescribed medication, but do not know for what	☐	☐	☐	☐

10 How often do you exercise?
(On average. Put an X in only one box)

☐ Never ☐ 2-3 times a week
☐ Less than once a week ☐ Nearly every day
☐ Once a week

11 About how many hours do you sit during a normal day?
(Both work hours and leisure time)

About ☐☐ hours *(e.g. 6 hours)*

	Yes	No
12 Do you have physical pain now that has lasted more than <u>6 months</u>?	☐	☐

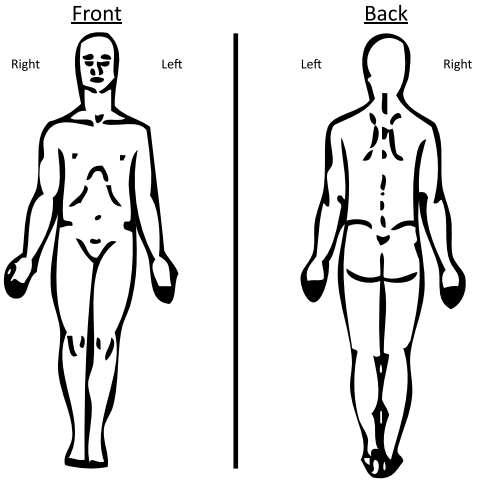
13 If yes, how strong has your physical pain been during the last <u>4 weeks</u>?

No pain ☐ Very mild ☐ Mild ☐ Moderate ☐ Strong ☐ Very strong ☐

BRIEF PAIN INVENTORY (SHORT FORM)

	Yes	No
14 Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain <u>today</u>?	☐	☐

15 On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



Survey number/ID:

16 Please rate your pain by marking the box beside the number that best describes your pain <u>at its worst</u> in the last 24 hours.

No pain									Pain as bad as you can imagine
1	2	3	4	5	6	7	8	9	10

17 Please rate your pain by marking the box beside the number that best describes your pain <u>at its least</u> in the last 24 hours.

No pain									Pain as bad as you can imagine
1	2	3	4	5	6	7	8	9	10

18 Please rate your pain by marking the box beside the number that best describes your pain <u>on the average</u>.

No pain									Pain as bad as you can imagine
1	2	3	4	5	6	7	8	9	10

19 Please rate your pain by marking the box beside the number that tells how much pain you have <u>right now</u>.

No pain									Pain as bad as you can imagine
1	2	3	4	5	6	7	8	9	10

20 What treatments or medications are you receiving for your pain?

Please specify.

21 In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

No relief									Complete relief
10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

22 Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

22.1 General activity

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

22.2 Mood

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

22.3 Walking ability

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

22.4 Normal work
(includes both work outside the home and housework)

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

22.5 Relations with other people

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

22.6 Sleep

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

22.7 Enjoyment of life

Does not interfere									Completely interferes
1	2	3	4	5	6	7	8	9	10

23 Exposure to a stressful event or situation (either short or long lasting) of exceptionally threatening or catastrophic nature is likely to cause pervasive distress in almost anyone. Examples of such difficult and frightening experiences are: being assaulted, or witnessing other people being hurt or killed.

	Yes	No
Have you experienced any of these or some other terrifying event(s)?	☐	☐

Survey number/ID:

IMPACT OF EVENTS SCALE - REVISED (IES-R)

INSTRUCTIONS: Below is a list of difficulties people sometimes have after stressful life events. Please read each item, and then indicate how distressing each difficulty has been for you **during the past seven days** with respect to _____ (event) that occured on _____ (date). How much have you been distressed or bothered by these difficulties?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
24.1 Any reminder brought back feelings about it.	0	1	2	3	4
24.2 I had trouble staying asleep.	0	1	2	3	4
24.3 Other things kept making me think about it.	0	1	2	3	4
24.4 I felt irritable and angry.	0	1	2	3	4
24.5 I avoided letting myself get upset when I thought about it or was reminded of it.	0	1	2	3	4
24.6 I thought about it when I didn't mean to.	0	1	2	3	4
24.7 I felt as if it hadn't happened or wasn't real.	0	1	2	3	4
24.8 I stayed away from reminders of it.	0	1	2	3	4
24.9 Pictures about it popped into my mind.	0	1	2	3	4
24.10 I was jumpy and easily startled.	0	1	2	3	4
24.11 I tried not to think about it.	0	1	2	3	4
24.12 I was aware that I still had a lot of feelings about it but I didn't deal with them.	0	1	2	3	4
24.13 My feelings about it were kind of numb.	0	1	2	3	4
24.14 I found myself acting or feeling like I was back at that time.	0	1	2	3	4
24.15 I had trouble falling asleep.	0	1	2	3	4
24.16 I had waves of strong feelings about it.	0	1	2	3	4
24.17 I tried to remove it from my memory.	0	1	2	3	4
24.18 I had trouble concentrating.	0	1	2	3	4
24.19 Reminders of it caused me to have physical reactions, such as sweating, trouble breathing, nausea, or a pounding heart.	0	1	2	3	4
24.20 I had dreams about it.	0	1	2	3	4
24.21 I felt watchful and on-guard.	0	1	2	3	4
24.22 I tried not to talk about it.	0	1	2	3	4

Survey number/ID:

GHQ-12

25 We would like to know how you have been feeling the last couple of months. Please mark the option that best suits your situation.

During the last two weeks, have you:

25.1 Been able to concentrate on what you're doing?	Better than usual	As usual	Less than usual	A lot less than usual
25.2 Lost much sleep over worry?	Has not happened	Not more than usual	More than usual	I slept a lot less than usual
25.3 Felt that you are playing a useful part in things?	More than usual	As usual	Less than usual	A lot less than usual
25.4 Felt capable of making decisions about things?	More than usual	As usual	Less than usual	A lot less than usual
25.5 Felt constantly under strain?	Not at all	Not more than usual	More than usual	A lot more than usual
25.6 Felt you couldn't overcome your difficulties?	Not at all	Not more than usual	More than usual	A lot more than usual
25.7 Been able to enjoy your normal day to day activities?	More than usual	As usual	Less than usual	A lot less than usual
25.8 Been able to face up to your problems?	Better than usual	As usual	Less than usual	A lot less than usual
25.9 Been feeling unhappy or depressed?	Not at all	Not more than usual	More than usual	A lot more than usual
25.10 Been losing confidence in yourself?	Not at all	Not more than usual	More than usual	A lot more than usual
25.11 Been thinking of yourself as a worthless person?	Not at all	Not more than usual	More than usual	A lot more than usual
25.12 Been feeling reasonably happy for day-to-day activities?	More than usual	As usual	Less than usual	A lot less than usual

THANK YOU FOR ANSWERING THESE QUESTIONS! PLEASE MAKE SURE TO RETURN THIS FORM TO THE PERSON WHO GAVE IT TO YOU BEFORE LEAVING.

Survey number/ID:

CHART

PAAI

Questions that will be used for evaluation of PAAI group interventions

(Sarkadi et al in Sweden)

1. How was it to be contacted by SMS?
2. How was it like to participate in the group?
3. What has been important for you in the group sessions?
4. Would you have liked more/less of something in the group?
5. Did you feel that any of the exercises were not relevant for you? If so which?
6. Did you feel that any of the exercises were difficult to carry out for you? If so, which?
7. Which exercise did you feel was the most helpful?
8. Did you get injuries or other negative consequences due to your participation in the group sessions?
9. Did you feel comfortable in the group? Explain, what made you feel this way?
10. Can you tell me about the relationships in the group?
11. Have you made some new friends within the group?
12. Have you met with group members outside the group sessions that you did not know before?
13. Would you recommend the group to someone your age? Why or why not? What would you say to others?
14. Anything else you want to tell us.

CHART

TRT

Questions that will be used for evaluation of TRT group interventions

(Sarkadi et al in Sweden)

1. How was it to be contacted by SMS?
2. How was it like to participate in the group?
3. What has been important for you in the group sessions?
4. Would you have liked more/less of something?
5. How has it felt like to hear others tell their stories?
6. What have you learned about how people can react after traumatic experiences/events?
7. What can you do when you feel stressed, scared, have trouble sleeping or you are thinking of the things you have experienced? Describe.
8. Did you feel comfortable in the group? Explain, what made you feel this way?
9. Can you tell me about the relationships in the group?
10. Have you made some new friends within the group?
11. Do you meet them outside the group sessions?
12. Would you recommend the group to someone your age? Why or why not? What would you say to others?
13. Anything else you want to tell us.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Fredrik Rongved	55978498	20.06.2018	2018/603/REK vest
			Deres dato:	Deres referanse:
			21.05.2018	

Vår referanse må oppgis ved alle henvendelser

Esperanza Diaz
Inst Global helse og sammfunsmedisin/NAKMI

2018/603 Effekt av gruppe fysioterapi og gruppe psykoterapi på fysisk og psykisk helse blant Syriske flyktninger med smerter eller post traumatisk symptomer.

Institutions responsible for the research: Folkehelseinstituttet, Universitetet i Bergen
Principal investigator: Esperanza Diaz

With reference to your application and your feedback dating 21.05.18 regarding the above-mentioned project. The Chair of REC West reviewed the application pursuant to The Health Research Act § 10.

Project descriprion (original):
Syria is now the 11th country of origin for immigrants in Norway. Although our knowledge of the health needs of asylum seekers and refugees is still incomplete, several studies suggest a high degree of chronic pain disorders and mental health symptoms. In this project, two group-based treatment interventions, developed in close collaboration with users and providers, will be tested in a randomized control study design. One intervention is physiotherapy based and the other based on psychological therapy (teaching recovery techniques). Among resettled asylum seekers and refugees, our primary aim is to separately study the effect on both physical and mental health of a) a physiotherapy activity and awareness intervention for participants with pain disorders and b) Teaching recovery techniques for participants with post-traumatic symptoms. Our secondary aim is to analyse the processes by which the interventions improve health. Third, cost effectiveness analyses will be conducted

Assessment
Requested feedback

REC West requested feedback on the following points:

- A new protocol that explains the necessity of all the questions.
- Name of the key cooperators added to the project.
- Add a project member with clinical experience in psychotherapy.
- A description of readiness in case of reactivation of trauma.
- A third information sheet.
- Revised information sheets.

Feedback

The project group have given feedback on the above-mentioned points. A revised protocol is attached along with revised questionnaires and information sheets. A third information sheet is also attached.

The group have described how they will handle a situation where a participant has trauma reactivated. This is described in the feedback schema, as well as being commented in the protocol.

Key cooperators and a project member with clinical experience is now added to the project. They are the following:

- Two physiotherapists at Bergen municipality: Rolf Vårdal and Line Merete Giusti.
- Two psychologists at Bergen municipality: Stine Laberg and Ingvild Hellsøy.
- Psychologist Unni Marie Heltne at the Center for Crisis Psychology has long clinical experience with this patient group and will be involved in the project.

In addition to these added project members, the project group would like to note that research members Esperanza Diaz and Lars Fadnes work part time as General Practitioners in Norway. This adds to the general clinical competence of the team.

The project group have also accepted the suggestion from the committee regarding anonymization. Finally, to avoid any misunderstandings, they've pointed out that the randomization will happen *within* each treatment group.

The Chair of REC West assessed the feedback.

Assessment

REC West has no further comments to this project.

Decision
REC west approves the project in accordance with the application and its feedback.

Further Information
The approval is valid until 31.12.2023. A final report must be sent no later than 31.06.2024. The approval is based on the grounds that the project is implemented as described in the application and the protocol, as well as the guidelines stated in the Health Research Act. If amendments need to be made to the study, the project manager is required to submit these amendments for approval by REC via the amendment form.

The decision of the committee may be appealed to the National Committee for Research Ethics in Norway. The appeal should be sent to the Regional Committee for Research Ethics in Norway, West. The deadline for appeals is three weeks from the date on which you receive this letter.

Best regards

Marit Grønning
Prof dr.med.
Chair

Fredrik Rongved
advisor

Kopi til: reksoknad@fhi.no; post@uib.no

Other publications related to the CHART project

The candidate contributed to these other publications related to the CHART project by:

- Contributing to the recruitment of participants and data collection
- Discussion of the findings
- Commenting the manuscripts from the first draft and through several rounds until their publication.
- Read and approved the final manuscripts.

1. Article - Health status and use of medication and their association with migration related exposures among Syrian refugees in Lebanon and Norway: a cross-sectional study
Elisabeth Marie Strømme, Jasmin Haj-Younes, **Wegdan Hasha**, Lars T. Fadnes, Bernadette Kumar, Jannicke Igland &Esperanza Diaz

2. Article - Changes in health among Syrian refugees along their migration trajectories from Lebanon to Norway: a prospective cohort study
E.M.Strømme , Haj-Younes , **W.Hasha** , L.T.Fadnes , B.Kumar , Igland , E.Diaz

3. Article - Changes in self-rated health and quality of life among Syrian refugees migrating to Norway: a prospective longitudinal study
Jasmin Haj-Younes , Elisabeth Marie Strømme ,Jannicke Igland , Bernadette Kumar , Eirik Abildsnes , **Wegdan Hasha** , Esperanza Diaz

4. Article - Use of health care services among Syrian refugees migrating to Norway: a prospective longitudinal study
Jasmin Haj-Younes , Elisabeth Marie Strømme ,Jannicke Igland , Eirik Abildsnes, Bernadette Kumar, **Wegdan Hasha** , Esperanza Diaz

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