Behaviour change interventions in primary health care

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Avhandling for graden philosophiae doctor (ph.d.)
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Contents

Abstract

As part of a public health promotion strategy, and in order to prevent non-communicable diseases (NCDs), the Directorate of Health recommends that Norwegian municipalities establish Healthy Life Centres (HLCs). This thesis builds on two studies that aim to: 1) find evidence of effect from interventions similar to the HLCs' interventions and explore if intervention characteristics could explain differences in effect between studies, and 2) evaluate the effects of HLC interventions.

In Study 1, we performed a systematic review of 48 randomised controlled trials (RCTs) of diet and physical activity interventions. We performed meta-analyses of 50 short-term (ES 0.37) and 32 long-term results (ES 0.24). Meta-regression analyses revealed that using several behaviour change techniques (BCTs), and especially the BCTs *goal setting of behaviour* or *self-monitoring of behaviour,* were associated with positive results at both short and long-term. Several other BCTs were associated with a long-term effect. There was evidence that a patient-centred and autonomous supportive approach in counselling seemed important to maintain change over time. In sum, interventions similar to the HLCs' interventions were modestly effective in changing behaviour in the short-term, with reduced effect long-term. These results may support the design and implementation of HLC interventions and help to identify the competence needed in counselling for maintenance of change.

In Study 2, we evaluated the effect of HLCs' interventions on physical activity, self-reported health and quality of life, quality of diet and diet behaviour, use of tobacco, sleep pattern, and body image. We designed a six-month randomised controlled trial (RCT) with a longitudinal follow-up 24 months after baseline. We recruited 118 participants (35% of those invited). The participants were predominantly middle-aged, obese, physically active, females motivated for change. Reasons for attendance were: being overweight, wanting to increase physical activity, to have a healthier diet, and to address musculoskeletal and mental health challenges. At the start of the trial,

70% of participants did 150 minutes of moderate to vigorous physical activity (MVPA) per week. The HLC interventions had no effect on the amount of time spent in MVPA or in sedentary behaviour after six months. However, those less physically active in the intervention group significantly increased their activity levels, as compared with the less active in the control group. The drop-out rate was 30%, and participants with mental health issues, musculoskeletal challenges or chronic somatic disease were more likely to leave the study.

The HLCs recruited participants with lower education and income as intended. It is unlikely that interventions that encompass people who are already physically active will improve population health or mitigate social differences in health. The differences we identified in physical activity between educational groups seemed to widen during follow-up, and the interventions did not mitigate these differences.

Norwegian abstract – Sammendrag

Som et ledd i en helsefremmende strategi og for å forebygge ikke-smittsomme sykdommer, anbefaler Helsedirektoratet kommunene å etablere Frisklivssentraler (FLSer). Avhandlingen er bygget på to forskningsstudier som har som mål å: 1) søke vitenskapelig bevis for at intervensjoner som ligner på FLSenes tilbud har effekt, og identifisere om trekk ved intervensjonen kan forklare forskjeller i resultat mellom studiene, og 2) evaluere FLS tilbudenes effekt.

Studie 1 er en systematisk kunnskapsoppsummering av 48 randomiserte kontrollerte studier av intervensjoner for sunnere kost og økt fysisk aktivitet. I metaanalysene inngikk 50 korttidsresultat (ES 0.37) og 32 langtidsresultat (ES 0.24). Meta regresjonsanalyser viste at det å bruke mange endringsteknikker, og spesielt å *sette mål for adferd* eller *registrere egen adferd,* var forbundet med et positivt resultat både på kort og lang sikt. Flere andre endringsteknikker var knyttet til langtidseffekt. En personorientert og autonomistøttende tilnærming i veiledning synes viktig for å vedlikeholde endring over tid. Intervensjonene som likner på FLSenes intervensjoner viste moderat effekt på atferdsendring etter intervensjonen, men effekten avtok over tid. Studiens resultat kan være til hjelp i design og implementering av FLS intervensjoner, og bidra til å identifisere nødvendig kompetanse i veiledning for varig endring.

I studie 2 evaluerte vi effekten av FLSenes tilbud på fysiske aktivitet, selv-rapportert helse og livskvalitet, kost og spisevaner, tobakksbruk, søvn og kroppsoppfattelse, designet vi en seks måneders randomisert kontrollert studie med en longitudinell undersøkelse 24 måneder etter oppstart. Vi rekrutterte 118 deltakere (35% av alle spurte). Majoriteten av deltakerne var middelaldrende, overvektige, fysisk aktive kvinner motivert for endring. Som grunner for deltakelsen oppga de overvekt, fysisk aktivitet, sunnere kost, muskelskjelett- eller mentale plager. Allerede før start, hadde 79% 150 minutter per uke med moderat til høy fysisk aktivitet (MHFA), og studien fant ingen forskjell på MHFA eller stillesitting etter seks måneder. Imidlertid økte de

i intervensjonsgruppen med lavest MHFA sin aktivitet signifikant, sammenlignet med de med lavest MHPA kontrollgruppen. Omtrent 30% av deltakerne falt ut av studien, og spesielt personer med mentale-, muskelskjelettplager eller kronisk somatisk sykdom.

I tråd med intensjonen, rekrutterte FLSene deltakere med lav utdanning og inntekt. Imidlertid er det ikke sannsynlig at intervensjoner for allerede fysisk aktive personer vil fremme folkehelsen eller utjevne sosiale forskjeller i helse. Det kan synes som at forskjeller i fysisk aktivitet mellom utdanningsnivå økte over tid og at tilbudet ikke klarte å utligne denne forskjellen.

List of publications

Samdal GB, Eide GE, Barth T, Williams G, Meland E. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults: systematic review and meta-regression analyses. International Journal of Behavioral Nutrition and Physical Activity. 2017;14(1):42.

Abildsnes E, Meland E, Mildestvedt T, Stea TH, Berntsen S, Samdal GB. The Norwegian Healthy Life Study: protocol for a pragmatic RCT with longitudinal follow-up on physical activity and diet for adults. BMC Public Health. 2017;17(1):18.

Samdal GB, Meland E, Eide GE, Berntsen S, Abildsnes E, Stea TH, et al. Participants at Norwegian Healthy Life Centres: Who are they, why do they attend and how are they motivated? A cross-sectional study. Scandinavian Journal of Public Health. 2018;0(0):1403494818756081.

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Selected abbreviations

ANCOVA Analysis of covariance

BCT Behaviour change techniques

BCTTv1 Behaviour Change Techniques Taxonomy version 1

BMI Body Mass Index

BOCF Baseline-observation-carried-forward

CHD Coronary heart disease

CI Confidence Interval

DLW Double labelled water

EE Energy expenditure

ET Endringsteknikk

ERS Exercise referral scheme

ES Effect size

GP General practitioner

HLC Healthy Life Centre

I^2 Heterogeneity index

ICC Intraclass correlation coefficient

KMI Kroppsmasseindeks

MHFA Moderat til høy fysisk aktivitet

MVPA Moderate to vigorous physical activity

MET Metabolic equivalent

MI Motivational interviewing

NCD Non-communicable disease

PA Physical activity

PAR Physical activity referral scheme

RCT Randomised controlled trial

R^2 Explained between-study variance

SES Socioeconomic status

SD Standard deviation

SDT Self-determination theory

SPSS Statistical package for the social sciences

SWA SenseWear Armband Mini

TTM Trans theoretical model

1. Introduction

1.1 General introduction

In 2012, I coordinated a working group that presented a model for a new Healthy Life Centre (HLC) across the municipalities of Fjell, Sund and Øygarden, on the West coast of Norway. As a special adviser at the Haukeland University Hospital, I witnessed a change in the Norwegian government's public health policy, including an emphasis on local governments taking responsibility for public health across all domains, with the intention of preventing the development of non-communicable diseases (NCDs). As part of this policy, the municipalities became responsible for promoting healthy behaviours for people at risk. I was curious to know more about the evidence base for the design of these interventions. What methods and techniques had proven effective in individual counselling for behaviour change? In 2013, based on initial funding from Haukeland University Hospital, I started my Ph.D, and due to our common interest in Motivational Interviewing (MI) and Self-determination theory (SDT), I met with Eivind Meland at the Department of Global Public Health and Primary Care, University of Bergen. Together with Eirik Abildsnes in Kristiansand, they planned to evaluate HLCs. I was included in the research group that developed an application to The Research Council of Norway. The Norwegian Healthy Life study received funding from 2014 to 2017.

1.2 Search strategy for the thesis

The search for theoretical and scientific evidence to form the basis of this Ph.D thesis began in 2013 with the systematic search for diet and physical activity intervention studies as part of writing a systematic review. (The Method section presents a full description of the systematic search.) The search revealed a variety of studies. The papers, of which many were excluded in the review process, contributed later to my learning and understanding of the field, including papers connected to exercise

referral schemes (ERS) in Great Britain. I searched the reference lists for additional knowledge. The results were later updated by automatic e-mail notifications of new publications via Medline, Google and Google Scholar using the terms *physical activity referral*, *physical activity referral schemes, exercise referral scheme, behaviour change techniques, frisklivssentral,* and *Behaviour Change Techniques Taxonomy version 1(BCTTv1*). A search for studies and grey literature related to the Norwegian HLCs started on the Norwegian Directorate of Health's website: https://helsedirektoratet.no/folkehelse/frisklivssentraler. In addition, I explored these websites; Self-determination theory (http://selfdeterminationtheory.org/), Centre for Behaviour Change, London Global University (http://www.ucl.ac.uk/behaviour-change). My search ended in September 2018.

1.3 The Norwegian Healthy Life Centre

Norway supports the World Health Organization's (WHO) global action plan for prevention and control of NCDs (1). In 2012, a Public Health Report followed by a Public Health Act, called for a *Health in all policies* approach. The report increased local government responsibility for public health care (2, 3). Compared with WHO's global action plan against NCDs, the new Norwegian NCD strategy placed a strong emphasis on individualised preventive measures towards physical activity, healthy diet, tobacco cessation, and reduced alcohol consumption (4). The government recommends that municipalities develop a new primary health care service for people at risk of NCDs, or for those who have had disease and need support in order to change their health behaviour (5). Through economic incentives from the government over several years, the service has spread into routine practice.

This new health service arena is called Healthy Life Centre (HLC) (Frisklivssentral). The HLCs aim to recruit socioeconomically disadvantaged groups, and to support behaviour change through individual and group-based interventions. Socioeconomic inequalities in mortality and life expectancy in Norway are comparable to other

European Countries, but unlike Spain, Scotland, England and Wales who showed a reduction in absolute inequalities in mortality over the two last decades, this outcome is absent in Norway and Finland. In addition, there is a widening of the relative inequalities in mortality in Norway, meaning Norwegians living in a higher socioeconomic position bettered their situation more than those living at the lower level (6).

The HLCs were also intended to be a resource centre for the promotion of public health in general in the municipality, e.g. for schools, kindergarten or workplaces. In 2016, more than 57% of municipalities had an HLC service, an increase of 118% from 2011-2014 (7). Public health insurance covers all costs for users of HLCs, however some HLCs do request a small fee (ca. €50) with the intention of increasing commitment to the programmes they offer.

The Directorate of Health provides general recommendations with basic principles for design and implementation of the HLC, targeting both local decision-makers and leaders, as well as personnel delivering the interventions and counselling (8). However, how the HLCs are organised in the primary health care system, with whom, and how they cooperate with other public services, private organisations, consumer organisations, the voluntary sector, and the exact content of the interventions and duration of follow-up, vary according to local political priorities, resources and available professional competence.

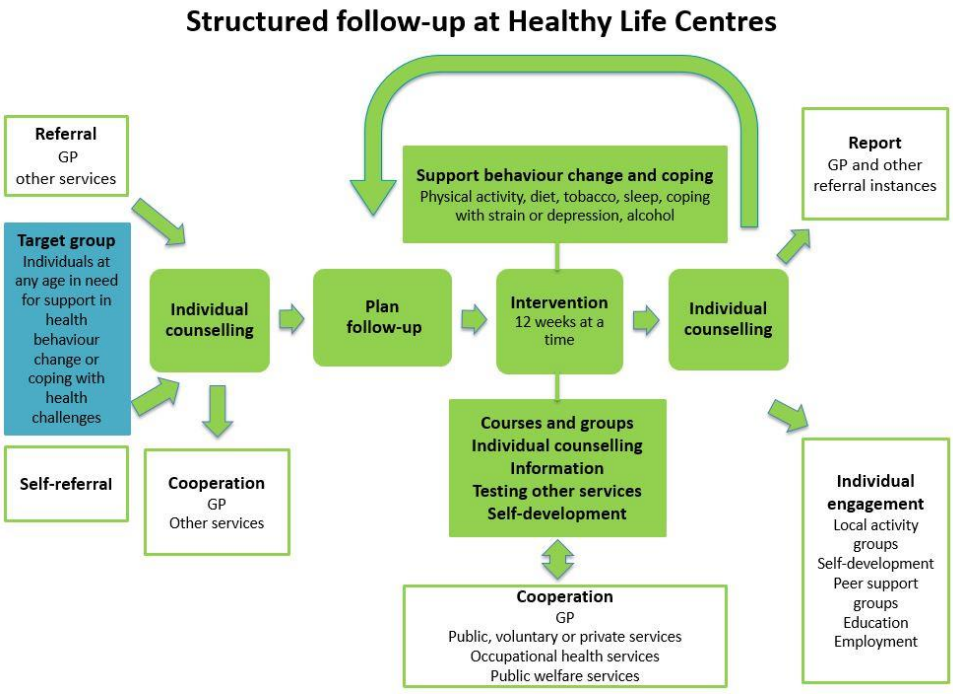

Figure 1 The Norwegian Healthy Life Centre model (5). The Norwegian Directorate of Health 2017 (by permission)

In the process of developing this research study, the research group explored local adaptations of the HLC model at six HLCs, looking at interventions, methods and available competence (9). The following presentation builds on the Directorate's recommendations and common intervention characteristics among these HLCs.

The HLC model consists of: 1) Referral by a general practitioner (GP), other public personnel or self-referral; 2) individual counselling at entry and exit based on motivational interviewing (MI); 3) support through behavioural change interventions promoting physical activity, healthy diet or smoking cessation for a, 4) 12-week intervention period (prescription) (Figure 1) (8). The physical activity, diet and tobacco cessation interventions are based on national recommendations within each

domain (10, 11). The Directorate of Health offers professional development workshops and has designed Healthy Eating and Stop Smoking interventions which are ready for implementation. The counsellors' professional backgrounds vary and may include physiotherapists, nurses trained in public health or psychiatry, occupational therapists, or trained lifestyle counsellors. Some have a bachelor's or master's degree in nutrition, physical activity or health promotion.

The individual MI counselling (12) (30-60 minutes) at introduction and exit may also include techniques from cognitive behavioural therapy (8). The Directorate of Health recommends that counsellors start the sessions by acknowledging the participant's perspective of health, offering information about health consequences, and presenting the intervention support. Based on readiness to change (13), results from a fitness test and a discussion about personal barriers/facilitators for change, the participant and counsellor agree on a goal for behaviour change. Some HLCs confirm behaviour goals in a written action plan. In addition, the Directorate of Health encourages the use of free self-help material, e.g. recipes and cookbooks, web-based applications for self-monitoring of physical activity, or the national tobacco cessation app. A physical therapist (or other professional) facilitates social support for physical activity through group-based interventions (Nordic walking, light strength conditioning, stretching, games), which often take place outdoors regardless of weather. Based on an individual's health and limitations, the therapist instructs and demonstrates appropriate physical activity. The participants must attend a minimum of two physical activity group sessions a week. Only a few HLCs offer sessions both in the daytime and in the evening. Some HLCs organise exercise groups exclusively for HLC participants, while others cooperate with public exercise groups and facilities in the municipality. The participants are offered a group-based educational course on Healthy Eating (10 hours) by a nutrition expert, including meal regularity, composition and portion size, and how to read food labels. Some HLCs include demonstrations of meal preparation and some show how to make healthy meals. The HLCs also provide group-based smoking cessation interventions.

After 12 weeks, a second individual counselling session provides the opportunity to review behaviour goals. Improvements in outcome of behaviour, e.g. fitness, wellbeing, health, or weight loss are evaluated. The counsellors offer feedback, and praise efforts and results in order to build self-efficacy for change. The majority of HLC prescriptions last more than 12 weeks (14). If there is a need for further or another type of intervention, the participant may extend the prescription period several times, up to one year. Towards the end, the counsellors encourage transfer to readily available local resources, such as sports organisations or leisure centres, in order to support maintenance of change in physical activity.

1.4 What are the health benefits of physical activity in adults?

Physical activity is associated with positive effects on mental health, reducing stress, anxiety and depression (15), and improving mental wellbeing (16). Physical activity is also fundamental in energy balance, weight control (17), and promotes muscle strength, fitness and bone health in adults (15). An active daily life is associated with cardiovascular health and longevity, regardless of whether the activity is performed as systematic exercise or not (18).

In line with WHO's recommendations, the Norwegian guidelines for physical activity recommend that adults take a minimum of 150 minutes at moderate intensity, or 75 minutes at vigorous intensity per week, or a combination of these (MVPA). MVPA may be performed in a series of at least 10-minute bouts as an alternative to one continuous longer bout. Prolonged sedentary time should be reduced. The recommendation also includes muscle-strengthening activities two days per week (11, 15, 19).

Only 32% of Norwegian adults achieve the recommended amount of physical activity per week. However, MVPA has increased 10% the last six years (20). Almost twice as many individuals with a high level of education were active at the recommended

level, compared to those with the lowest level of education. Physical *inactivity* is one of the leading global risk factors for morbidity and premature mortality and it is considered a major public health issue in combating NCDs e.g. cardiovascular disease, diabetes, cancer, and hypertension (1, 21). Globally, the number of deaths caused by inactivity is comparable to deaths caused by tobacco and obesity. The attributable risk of physical inactivity accounts for 6-10% of major NCDs (21). Those who are active, but at a lower level than recommended (about 90 minutes per week), may still live 3 years longer (22). A population based study found no association between total sitting time (at work, at home, in transit, or in leisure time) and diabetes risk, except for physically inactive people (23).

The health benefit of short bouts of physical activity has been advocated for over 20 years. When American guidelines for physical activity in 2008 recommended MVPA in bouts of at least 10 minutes' duration to achieve significant health benefits, the majority of available data were based on self-reported instruments making it hard to identify the possible health effects of shorter bouts (24). One early study that compared MVPA in bouts with MVPA in non-bouts (using an accelerometer) found that MVPA in sessions lasting less than 10 minutes was associated with lower levels of obesity markers (25). However, MVPA in bouts was more time-efficient and more predictive than MVPA in non-bouts. A more recent study using an accelerometer to assess activity indicated that total MVPA with no requirements, compared with MVPA in 5-minute bouts, and MVPA lasting at least 10 minutes, reported that all three alternatives provided similar risk reduction for all-cause mortality (26). The results were supported in a recent systematic review. In this study, objectively measured light physical activity was associated with health outcomes in adults when adjusting for MVPA (27). This implies that incidental activity from all aspects of daily life may be beneficial for the least active. A good start for those at greater risk of developing chronic disease may be to take the stairs instead of the elevator, or to park further away from their destination and walk. It is predicted that scientific results

are likely to influence future physical activity guidelines and public health policies, e.g. in the use of urban design to promote physical activity as part of daily life (24).

1.4.1 Why are some people physically active and others not?

Genetics, evolutionary biology, and variations in physical activity throughout life are important determinants of physical activity at the individual level, along with age (inversely), male sex, health status, self-efficacy, previous experience of physical activity, and motivation (28). Ecological models of health behaviour causation also include determinants for physical activity at social, environmental, policy, and global levels (29). Figure 2 illustrates the inter-relation between determinants at an individual level and the social and physical environment. Being overweight is associated with lower levels of physical activity (30), but the causal directions are less clear (28, 31).

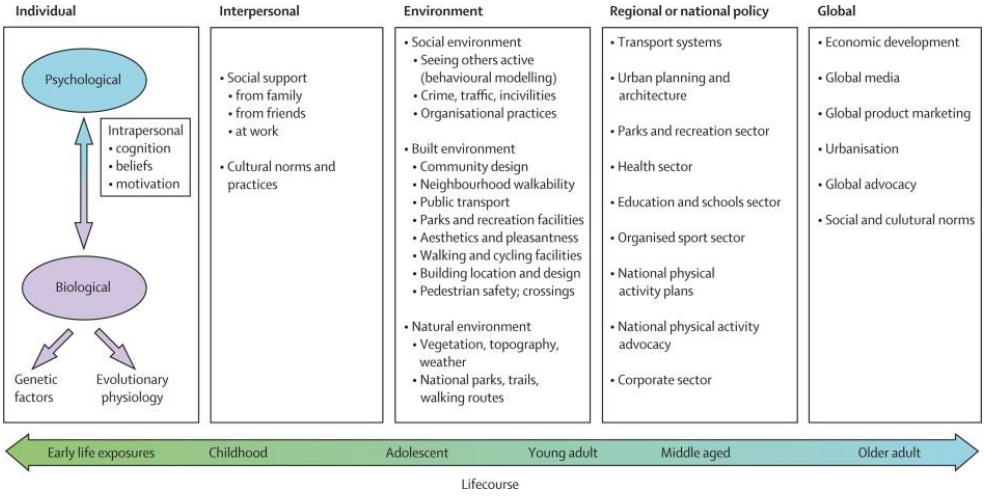

Figure 2 An ecological model of the determinants of physical activity (28).

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A multilevel public health strategy that balance an approach aimed at reducing risk factors in the population, with one directed at high-risk individuals, may offer the

best chance of success in increasing physical activity and reducing inactivity (1, 32, 33). Initiatives must be multi-sectoral in order to be effective, e.g. involve policy for urban planning, transport, workplaces, recreation, in addition to the health care system (11, 34). An example of such an approach is seen in the case of tobacco cessation (35). The WHO European Region encourages member states to implement evidence-based initiatives to increase physical activity, and to scale up their policies and interventions (34). As part of this effort, there is a call for individual physical activity interventions to be delivered in primary health care (15, 32). However, they recognise that there is a lack of knowledge about which programmes can be effectively implemented in a real-world setting (36).

1.4.2 What is physical activity and how do we measure it?

Physical activity is a set of behaviours and may be defined as any bodily movement produced by skeletal muscles that results in energy expenditure (EE) (37). Physical activity may be structured or incidental. Structured physical activity is planned activity, which aims to improve or maintain health and fitness, such as muscular strength, endurance, flexibility, and cardiorespiratory capacity. The term is often used synonymously with *exercise*. Incidental activity is the result of daily behaviours or movements at home, during transit, at work, and at leisure (37). Assessment of total physical activity should capture all domains.

A wide range of subjective and objective methods can assess a person's physical activity. The gold standard is direct observation or video recording of the persons who engages in physical activity, and to monitor or record the results (38). Subjective methods rely on the participant to recall (by survey, or face-to-face interview), or to log activities as they occur (38). Self-reported measures are often used because they are an inexpensive and reliable alternative to capturing structured activity, and they are applicable when dealing with a large number of individuals(38). However, the measures are subject to recall and social desirability bias. In addition, they have to be adapted to population and culture, and have low validity for assessing incidental or

lifestyle physical activity. Objective methods use wearable monitors to measure indicators of physical activity or EE (38). The most commonly used sensors are accelerometers or multi-sensing monitors and pedometers. Pedometers quantify steps and estimate walking distance. New models also estimate the amount of time spent active at different intensity levels. Accelerometers report frequency, duration, and intensity of physical activity movements. Accelerations may be measured in 1 plane (vertical), 2 planes (vertical and mediolateral or vertical and anterior-posterior), or 3 planes (vertical, mediolateral, and anterior-posterior) (38). The monitors are attached to the body (hip, ankle, wrist, or upper arm) with a strap. They can store data for weeks, and their use has increased in recent years (38). However, many do not track activities such as cycling, stair use and swimming, and they have a higher cost compared to self-reported methods. Handling and processing of raw data can also be challenging and may need technical competence (39).

The main data measure of accelerometers is a recall of body acceleration and deceleration (38). Raw accelerometer data is most often recorded in units of acceleration due to gravity, and expressed as acceleration in meters per second squared. This is later transformed into other units, e.g. counts per second or counts per minute. Because the different accelerometers handle raw data differently, the actual counts as a derived unit is dependent on the individual accelerometer (38). Accelerometers must be calibrated to translate monitor signals into EE units or activity intensity categories (38). The operation results in a prediction equation or count thresholds for a particular intensity of the activity, and converts accelerometer values into physical activity outcomes. It is a substantial variability in the prediction equations across monitors, and it is important to acknowledge this limitations in outcome results (38).

Time spent at different levels of physical activity depend on how the cut-off points are defined. Common measures of interest from physical activity are EE in kilocalories, or the metabolic equivalent (MET) of the activity (25). One MET is represents the resting EE for a person weighing 70 kilos while sitting quietly. One

MET is defined as 3.5 mL $O_2 \cdot kg^{-1} \cdot min^{-1}$ or ≈ 250 mL/minutes of oxygen consumed (38). There is no consensus, but generally accepted, that time spent sedentary refers to 1 - 1.4 METs, physical activity at light intensity, 1.5 - 2.9 METs; moderate intensity, 3 - 5.9 METs, and vigorous intensity, ≥ 6 METs (39, 40). In order to get a good representation of a person's physical activity pattern, monitoring should continue over several days. Results from one study of older people, identified at least three days to be necessary (39).

There are several different body monitors on the market, among these ActiGraph and SWA (38, 41, 42). SWA includes a three axis accelerometer and adds multiple outcomes to results from the accelerometer (data from a heat flux sensor, skin temperature sensor, near body ambient temperature sensor, and a galvanic skin response sensor) (42). The SWA is tested and was found to identify different intensity levels of physical activity and sedentary behaviour between BMI subgroups (43). In a study of healthy adults engaged in a variety of low intensity activities, SWA had the advantage of being able to quantify energy expenditure (EE) for very low-intensity activities when compared to indirect calorimetry (44) which is a reference method for measuring EE under controlled conditions (38). Doubly labelled water (DLW) is considered an independent measure, and the gold standard, and the method measures total EE in free-living individuals over a period of one to three weeks. Details of the method are explained elsewhere (38). Two validation studies have compared SWA to DLW and indirect calorimetry in free-living adults (42, 45). Intraclass correlation coefficient (ICC) in the two studies was 0.81 ($p < 0.001$) and 0.73 ($p < 0.001$). This means that 81% and 73% of the variance in EE between the SWA and the more objective methods was due to individual differences in the subjects. However, the SWA underestimated daily EE by 4.7% and 9% respectively (45). In one study comparing SWA and ActiGraph to indirect calometry, both overestimated time in MVPA. ActiGraph also underestimated daily EE, and both monitors underestimated total EE (42). The findings indicate that the devices may not be accurate at an individual level, but when individual inaccuracies are grouped together and analysed,

the inaccuracies become less significant across the whole group. Using the same monitor across several time points will therefore identify change.

Higher intensity of physical activity increases oxygen consumption. Consequently, physical activity volume or total activity level over a defined time is estimated by multiplying dimensions of intensity, duration and frequency over a given time period. The relative intensity level for an individual person varies according to their level of cardiorespiratory fitness (38), and MET value varies according to sex, age and body composition. One of the most common output measures of physical activity assessment is the amount of time a person spends at a specified physical activity intensity level. The outcomes can be used to determine if the person meets recommended physical activity guidelines, e g. 150 minutes of MVPA per week (38).

1.5 Evidence for physical activity intervention by referral

Behaviour change interventions from primary health care or community settings have so far been inconclusive when it comes to demonstrating an effect on physical activity (14, 46, 47). The reviews show significant heterogeneity between studies, e.g. lack of consensus in main outcomes and how to measure the effect. The effectiveness of the interventions over time is also uncertain as the majority of the studies ended at 9-12 months (14, 48, 49). Lately, evidence suggests that targeting sedentary behaviour may be more successful (50, 51).

The physical activity interventions at the HLCs is the Norwegian model of what other countries have called *green prescription* (New Zealand), *exercise referral scheme* (ERS) or *physical activity referral scheme* (PAR) (United Kingdom), or *physical activity on prescription* (Sweden). The ERS are comparable to the HLCs as they generally consist of: 1) a referral from primary care to a third party, usually a leisure facility; 2) a programme of supervised physical activity, usually over a 10-12 week period, and 3) a consultation with an exercise specialist at entry to and exit from the programme (52).

The Norwegian HLCs are still under development with few research studies of participants and interventions. Research up until 2013 published in international peer-reviewed journals was limited to one prospective study (53). One study exploring the stakeholders' view identified several dilemmas, e.g. prioritising between individual prevention or general public health promotion (9). Another study raised doubt about whether the interventions provided sufficient support for adults with previous negative life experiences and low self-efficacy (54). Danish and Swedish evaluations of ERSs are not always comparable to the HLCs due to differences in target populations. The studies show no effect or have methodological limitations (55-57).

Internationally there has been considerable uncertainty as to the effectiveness of ERS for increasing physical activity, and not enough evidence to indicate whether exercise referral is more effective than other primary care interventions (14, 47, 58, 59). The critics apply to limitations in the short-term programmes, the lack of RCTs with follow-up data, the lack of objectively recorded physical activity, low adherence rates, lack of evidence on health outcomes, and cost effectiveness. Critics have also argued against the emphasis on leisure time and exercise groups, claiming that the preventive elements and balance of sedentary behaviour and activity in all aspects of daily life are overlooked (60, 61). Concerns have been raised about the widespread rollout of such programmes due to limited evidence (62). Despite the critics, ERSs have become increasingly popular.

Due to the considerable variation in content and delivery of the ERS service in the United Kingdom, participants did not receive a standard service (63). The interventions included different behaviour change theories and methods, and used different behaviour change techniques (BCTs), making it unclear to what extent the interventions reflected evidence-based practice (64). It was also difficult to compare the results between studies when the schemes varied in form, types of evaluation, results for different subgroups, with different reasons for referral (65). To account for this problem, the Welsh Government in 2012 decided to implement one single model across the country based on common guidelines (63). For methodological reasons, the

Welsh RCT included only sedentary individuals with a risk of coronary heart disease (CHD) or mental health problems. After 12 months, there were significant improvements in both physical and mental health and physical activity among participants with a risk of CHD. There was no increase in physical activity among those referred for mental health reasons, but the interventions reduced anxiety and depression. The study concluded that the scheme was effective for certain medical conditions and cost-effective in fully adherent participants (63, 66).

1.6 Theoretical frameworks for understanding behaviour change

The HLC model is not based on a theory of health behaviour or a theoretical framework for health behaviour change. The Directorate's basic recommendation does, however, mention several cognitive theories and presents the Transtheoretical model of change (TTM) as a way of understanding the process of changing, in addition to MI as a general counselling approach (8). This chapter presents theoretical frameworks and models for understanding health behaviour change and presents empirical evidence for methods and BCTs that may be relevant in the design and implementation of interventions at the HLCs.

Understanding how people behave does not automatically enable counsellors to help them make better choices. According to Kelly and Barker, public health government complicates matters when it implies that behaviour change is easy and intervention design and implementation is common sense (67). The common-sense approach to helping people change their behaviour relies on providing direct advice or *telling them what to do.* This approach is rarely sufficient. The underlying assumption claims that people lack knowledge and that improving knowledge changes attitude and creates an intention to change. The approach does not account for the many complex influences on behaviour, nor the social and cultural implications of behaviour. In order to understand the reasons why people do what they do, we need to understand

the individual behaviour in the context in which it occurs (67). The quality of the service can be improved by helping health professionals to design new interventions on evidence-based practice (68). Some countries do this by using national guidelines for best practice in counselling for behaviour change. The guidelines may define necessary competences and BCTs required across different behavioural domains, client groups and levels of intervention (52, 69-71).

In general, it is claimed that developing behaviour change interventions should be enhanced by applying formal theories and evidence generated by systematic evaluation of former interventions. These claims are not always supported by conclusive evidence (72). Few if any theories can fully predict a complex, multicomponent intervention's effectiveness. However, theories predict change by suggesting which targets (constructs or variables influencing behaviour) to try to change, such as self-efficacy, motivation or skills. Selecting appropriate BCTs to target the construct can optimise design, evaluation and learning (73). This requires knowledge of theoretical determinants of change. Health practitioners are seldom trained in the use of theories of behaviour change. Nor are they trained to identify relevant mechanisms and suitable BCTs to influence behaviour. Due to this and to insufficient resources, many practitioners move straight to implementation (74, 75). Common sense-based interventions rely on (arbitrary) counsellors' informal, experience-based theories of causal relations (74, 76). This means that all intervention designers use some kind of theory, whether they are formally recognised or based on personal experience of effect. However, they don't always explicitly state which theories they use (77, 78).

Some theorists claim that the best basis for designing behaviour change interventions is to combine informal and formal theories (79). Complex interventions work when the causal mechanisms are sufficiently suited for the local context to produce change (78). A programme theory may be defined as the logic model for how the intervention might work (79, 80). Effective application of programme theories relies

on well-informed judgements that take into account experience and knowledge of important causal mechanisms of change, in a local context.

A total of 83 theories/models are identified across psychology, sociology, anthropology, and economics that explain how human behaviour develops and is changed. The theories are often interconnected, have a considerable range of constructs, and are often overlapping (81, 82). Theories like theory of planned behaviour, social cognitive theory and the TTM are based on correlation analyses and were designed to predict behaviour (83). They were not designed as a framework for designing behaviour change interventions. The models treat individuals as rational actors and few studies have demonstrated how the models inform the design of behaviour change interventions. In addition, the theories explain why people initiate a behaviour but provide little explanation of how the initiation and maintenance of behaviour might differ (84).

More modern theories also take into account automatic processes and include constructs that are important in behaviour maintenance, such as habits, satisfaction with the outcomes of change and supportive environments (83). Such theories claim that people are likely to initiate change when their motivation is high and their opportunity costs are low. Most behaviour change interventions rely on influencing people's cognitions (e.g. outcome expectations), or skills, (e.g. by demonstration and practice of behaviour). It has been hypothesised that the decision to initiate behaviour is based on expected future outcomes and the ability to master changes (self-efficacy), but as time passes people shift their attention from expectations to their experiences with the new behaviour (84). A decision about whether to maintain a change involves an evaluation of whether the experiences are sufficiently desirable to support continued action. If people find that the new behaviour requires considerable self-regulatory resources, they may lose confidence and commitment. Consequently, BCTs that help people to initiate change do not necessarily have the same effect on behaviour maintenance. Thus, determinants of behaviour differ across phases of the behaviour change process (See Figure 3) (84, 85).

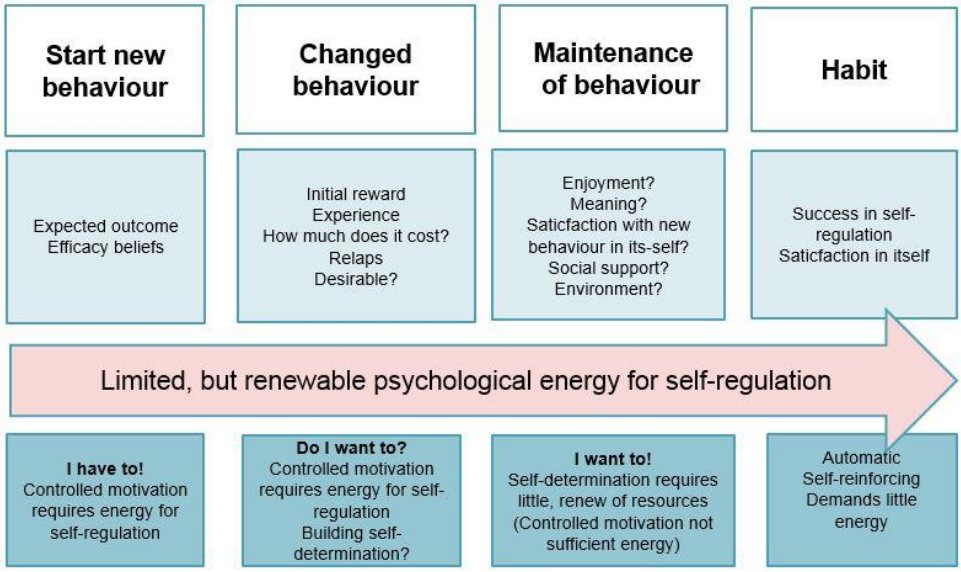

Figure 3 Determinants of behaviour across phases of the behavior change process illustrated by author based on (84)

A change in behaviour does not lead to health benefit unless the changes are maintained over time. A review paper summarizing 100 theories that explain *maintenance* of behaviour change identified these themes as important: 1) positive motives, e.g. personal, meaningful and acting in line with a new identity; 2) active self-regulation; 3) habit development; 4) physical or psychological resources, and 5) social support at individual, social or community level (85). *Self-regulation* may be defined as controlling the behaviour by inhibiting automatic behaviour, urges, emotions, or desires, and replacing them with a goal-directed response (85). Self-regulation is a limited, but renewable, cognitive resource that is drained when a person attempts to control his/her behaviour. Individuals differ in their skills to regulate behaviour when tasks are challenging, e.g. to cope with barriers, temptations and managing lapses. According to this perspective, people who are motivated by their own needs and desires, as opposed to those of others, find it is easier to sustain the new behaviour over time and they might actually enjoy it (Figure 3) (84).

1.6.1 A practical tool for planning behaviour change interventions

Developing theory and evidence-based interventions in the real world setting that includes interacting factors is a complex task. In the attempt to integrate previous work within behavioural and social science and to address the complexity of health behaviour, Michie and colleagues developed a framework to support professional intervention design. The framework explores the determinants of behaviour and matches evidence-based BCTs to these. According to this COM-B system, you need *capability*, *opportunity*, and *motivation* to perform the *behaviour*. Capability means being physically and psychologically capable of performing the actions. Opportunity is defined as the need for physical and social opportunity in the environment (86, 87). Motivation means being motivated to adopt the new, rather than the old, behaviour (involving reflective or automatic processes). The components can interact and behaviour can again influence capability, opportunity, and motivation through feedback loops (Figure 4).

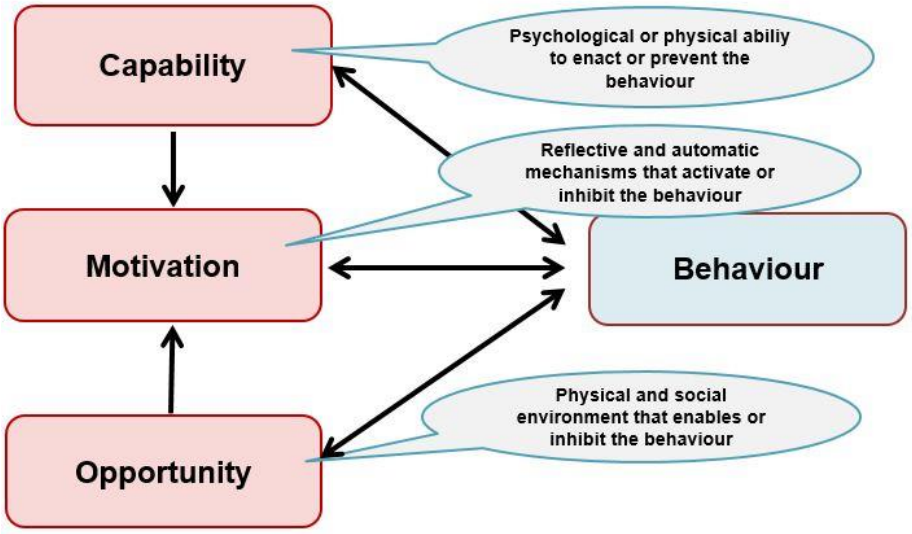

Figure 4 A framework for understanding behaviour: The COM-B system (87).

The COM-B system is the hub of a larger system called the Behaviour Change Wheel (BCW) where several intervention functions can be linked to specific BCTs (87). However, the BCW will not be presented further, except to say that the framework supports an ecological understanding of behaviour as no priority is placed on the individual, group or environment. The system or model can be applied in intervention design including environmental planning, legislation and fiscal measures to promote changes in behaviour, e.g in social systems or by public policy, in addition to traditional individual interventions.

1.6.2 Behaviour change techniques

Intervention components cover: who delivers the intervention, to whom, how often, and for how long, in what format and context, and with what content (88). The counsellors use different strategies when trying to change an individual's behaviour, motivations, or other factors that influence behaviour. Behaviour change techniques (BCTs) can be defined as coordinated strategies designed to change specific behaviour patterns (87). Recent developments within the science of behaviour change include a search for the effect of different techniques. Intervention design and implementation of content are often poorly or inconsistently described across studies making replication difficult. To overcome this, Michie and colleagues developed a taxonomy and a common language to describe the techniques included in an intervention (68, 89, 90).

Several reviews have used the taxonomy's standardised vocabulary to classify *the active ingredients* in counselling and applied meta-regression to explore the heterogeneity in effectiveness across physical activity and healthy eating interventions. While meta-analyses combine the results from several studies into pooled effect estimates, meta-regression provides a mean to investigate differences in effect size as a function of BCTs or other intervention characteristics. Reviews published up to 2017 used the first taxonomy, describing 26 BCTs (89), or the second, describing 44 BCTs (90). The latest version is an international consensus of

93 BCTs defined as the active content in behaviour change interventions (BCTTv1) (Figure 5) (91).

Grouping and BCTs	Grouping and BCTs	Grouping and BCTs
1. Goals and planning	**6. Comparison of behaviour**	**12. Antecedents**
1.1. Goal setting (behavior)	6.1. Demonstration of the behaviour	12.1. Restructuring the physical environment
1.2. Problem solving	6.2. Social comparison	12.2. Restructuring the social environment
1.3. Goal setting (outcome)	6.3. Information about others' approval	12.3. Avoidance/reducing exposure to cues for the behaviour
1.4. Action planning	**7. Associations**	12.4. Distraction
1.5. Review behavior goal(s)	7.1. Prompts/cues	12.5. Adding objects to the environment
1.6. Discrepancy between current behavior and goal	7.2. Cue signalling reward	12.6. Body changes
1.7. Review outcome goal(s)	7.3. Reduce prompts/cues	**13. Identity**
1.8. Behavioral contract	7.4. Remove access to the reward	13.1. Identification of self as role model
1.9. Commitment	7.5. Remove aversive stimulus	13.2. Framing/reframing
2. Feedback and monitoring	7.6. Satiation	13.3. Incompatible beliefs
2.1. Monitoring of behaviour by others without feedback	7.7. Exposure	13.4. Valued self-identify
2.2. Feedback on behaviour	7.8. Associative learning	13.5. Identity associated with changed behaviour
2.3. Self-monitoring of behaviour	**8. Repetition and substitution**	**14. Scheduled consequences**
2.4. Self-monitoring of outcome(s) of behaviour	8.1. Behavioural practice/rehearsal	14.1. Behaviour cost
2.5. Monitoring of outcome(s) of behaviour without feedback	8.2. Behaviour substitution	14.2. Punishment
2.6. Biofeedback	8.3. Habit formation	14.3. Remove reward
2.7. Feedback on outcome(s) of behaviour	8.4. Habit reversal	14.4. Reward approximation
3. Social support	8.5. Overcorrection	14.5. Rewarding completion
3.1. Social support (unspecified)	8.6. Generalisation of target behaviour	14.6. Situation-specific reward
3.2. Social support (practical)	8.7. Graded tasks	14.7. Reward incompatible behaviour
3.3. Social support (emotional)	**9. Comparison of outcomes**	14.8. Reward alternative behaviour
4. Shaping knowledge	9.1. Credible source	14.9. Reduce reward frequency
4.1. Instruction on how to perform the behaviour	9.2. Pros and cons	14.10. Remove punishment
4.2. Information about antecedents	9.3. Comparative imagining of future outcomes	**15. Self-belief**
4.3. Re-attribution	**10. Reward and threat**	15.1. Verbal persuasion about capability
4.4. Behavioural experiments	10.1. Material incentive (behaviour)	15.2. Mental rehearsal of successful performance
5. Natural consequences	10.2. Material reward (behaviour)	15.3. Focus on past success
5.1. Information about health consequences	10.3. Non-specific reward	15.4. Self-talk
5.2. Salience of consequences	10.4. Social reward	**16. Covert learning**
5.3. Information about social and environmental consequences	10.5. Social incentive	16.1. Imaginary punishment
5.4. Monitoring of emotional consequences	10.6. Non-specific incentive	16.2. Imaginary reward
5.5. Anticipated regret	10.7. Self-incentive	16.3. Vicarious consequences
5.6. Information about emotional consequences	10.8. Incentive (outcome)	
	10.9. Self-reward	
	10.10. Reward (outcome)	
	10.11. Future punishment	
	11. Regulation	
	11.1. Pharmacological support	
	11.2. Reduce negative emotions	
	11.3. Conserving mental resources	
	11.4. Paradoxical instructions	

Figure 5 The 93 Behaviour Change Techniques in BCTTv1.

The first review (101 studies) to use a taxonomy to identify effective techniques found no significant associations between BCTs and change in behaviour, although *self-monitoring of behaviour* explained the greatest amount of between-study heterogeneity among healthy adults (92). In another review (44 studies), the BCTs *Instruction* and *self-monitoring of behaviour*, *relapse prevention* and *practicing the behaviour* were associated with significant weight reduction in obese adults. *Provide general information* and *provide information on consequences* had a negative association. However, no BCTs were associated with change in physical activity (93). A systematic review of a diverse population (11 - 64 years old) (25 studies) found no effect of BCTs on behaviour, except that *providing feedback* had a negative association (94). According to Williams and French, six BCTs were associated with higher levels of physical activity across 24 studies of healthy older adults. Among these were *action planning*, *instruction* and *reinforcing efforts* for change of behaviour (95). Using several different BCTs has also been associated with increased effectiveness in type 2 diabetes, e.g. in a review of 17 studies and a study of participants' use of BCTs (96, 97). The rationale behind this is that interventions using a higher number of BCTs target several different aspects of the behaviour change process. Two reviews reported that using MI as a counselling approach was not associated with success (93, 98). According to Dombrowski and colleagues, volitional planning and action strategies were more effective than promoting personal motivation for change. In sum, the results of trying to identify effective BCTs have so far been conflicted, making recommendations about implementing specific BCTs difficult in intervention design.

Although the research field has started identifying BCTs used in interventions, few empirical studies have explored fidelity and the possible differences between planned and actual implementation. One study of fidelity in the ERS interventions revealed inconsistent use of a client approach, that goals had an outcome rather than a behavioural focus, e.g. the BCT *provide information* was often used, while one of the

most evidence-based BCTs *self-monitoring of behaviour,* was infrequently observed (99).

1.6.3 Motivational interviewing

In behaviour change interventions, professionals use different therapeutic approaches, or different communication styles. Motivational interviewing (MI) is not a theory or a model of behaviour change, but "*a collaborative conversation style for strengthening a person`s own motivation and commitment to change*" (12). MI consists of clearly described techniques, such as reflective listening, shared decision-making, rolling with resistance, eliciting change talk to assist the individual to explore and resolve their ambivalence or resistance to change in a non-judgemental way. MI is sometimes used synonymously with client-centred counselling. However, MI is not only client-centred, but also goal-driven and directive, as there is a clear behaviour outcome, e.g. stop smoking, be more physically active (12).

MI is proven as a promising approach to motivate for change in multiple health contexts and across numerous health behaviours, including PA and diet (100-105). Recent developments in the identification of techniques in MI resulted in the classification of 16 relational and 22 content based techniques unique to MI, and 16 that showed overlap with BCTTv1 (106). The results confirm that changes in motivation and behaviour are a result of both *intervention content* (what is said) and *interpersonal style* (how it is said) (107).

Originally, MI was developed to address a lack of motivation for change and was not intended to be a comprehensive approach to behaviour change. It makes little sense to only provide MI since this is a communication style for helping people move from ambivalence to motivation for behaviour change [32]. In addition, decisional balance, exploring both the pros and the cons of change, are often confused with MI. The decisional balance technique is contraindicated when the individual is ready for change because it might bring the conversation back to sustain talk (counter-change

talk) (108). Later developments within MI have strengthened planning for action and how to implement new and changed behaviours. However, many counsellors experience that the spirit of MI (compassion, collaboration, acceptance and evocation) can be generally applied when they move from building motivation to the more action-oriented support of self-regulation to avoid a more directive communication style [32, 42].

In addition to MI, the Norwegian Directorate of Health recommends the TTM as a conceptual model to explain why some people change while others do not (13). TTM highlights readiness for change by identifying psychological changes at different stages that precede behaviour change. Perception of barriers and benefits or pros and cons differ between stages. Yet this popular model is criticised by several researchers for its lack of empirical support for explaining and predicting change (71, 82).

Efforts are made towards linking MI with SDT due to conceptual overlap and similarities (109, 110). MI has been criticised for a lack of theory to explain why the method works and predicts change. SDT is presented as a theory that can explain how MI techniques support the participants' basic needs by allowing them the freedom to explore reasons for and against change (autonomy) in a non-judgmental context (relatedness) (109, 110).

Several studies of ERS report that MI is used in counselling for behaviour change (63, 111). However, process evaluation of the Welsh ERS identified serious problems with implementation of the interventions. The professionals did not deliver MI as intended. Data collection was substituted with client-centeredness. Some deemed MI unnecessary because the participants were already motivated for change. Behaviour change goals were unmeasurable (112, 113) and motivation increased as a result of support from other participants, and less as a result of counselling (78).

1.6.4 Self-determination theory

Self-determination theory (SDT) is one of several theories that explain the adoption of behaviour change and maintenance of change over time (114). According to this theory, there are three main types of motivation quality: *Intrinsic motivation* is when people do the behaviour for their own sake e.g. reading, playing music, being physically active because they find it enjoyable, fun or energising. *Extrinsic motivation* (controlled) is when behaviour is pressured by intrapsychic or interpersonal forces, e g. rewards, social acceptance, proving something to oneself, reduced risk of disease, or in order to follow doctor`s orders. *Amotivation* means that an individual lacks motivation to do the behaviour. SDT defines the different types of motivation along a continuum with intrinsic motivation and amotivation at opposite ends, and with extrinsic motivation in the middle. Many health behaviours, such as being more physically active, are extrinsically motivated in nature (109). Accordingly, a successful increase in physical activity will not be maintained over time if the reasons for doing the activity are mainly issues of control (e.g. a strong desire to be thin, look fit, or to do what one is told). Health-related behaviours are more likely to be initiated and maintained when the patient experiences self-determination (being autonomous) and acts according to personal meaning or value (identified motivation). The process of internalisation of motivation can be facilitated by counsellors when they maximise three basic psychological needs: the participant`s experiences of autonomy, competence and relatedness (Figure 6) (114).

Health personnel may boost the individual's basic needs by using various BCTs and thus encourage the behaviour to become relatively more internalised, regulated and valued over time. *Autonomy* is promoted when the participant feels volitional, has a choice and acts on free will. Autonomy can be supported by exploring individual values and offering choices. *Competence* is achieved when the participant is able to perform the behaviour and can be enhanced when the counsellor supports the participant's self-regulation skills. *Relatedness* is built when the participant feels understood and valued by significant, important others. Relatedness can be improved

when the counsellor practices reflective listening and expresses empathy. The emphasis on the relationship between participant and counsellor illustrates how the social context may support or thwart optimal motivation.

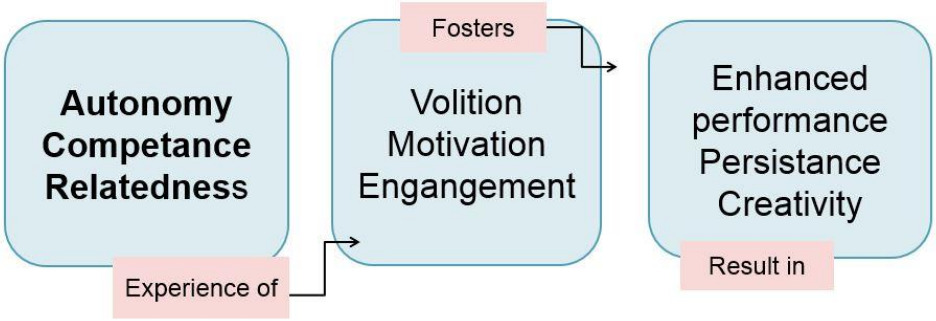

Figure 6 Model for lasting health behaviour based on Self-determination theory.

Need-supportive interventions and a more autonomous regulation of behaviour have predicted success in many domains, including long term weight control (115), tobacco dependence (116), psychological well-being (117), healthy eating (118), and exercise (119-122). Moreover, autonomous reasons for physical activity have been shown to spread to and affect other behaviour domains, like the regulation of eating (123). Body dissatisfaction, obesity and dysfunctional eating have been associated with a controlled regulation of eating behaviour (124).

1.6.5 Professionals or technicians?

Efforts to identify effective BCTs through meta-regression analyses have been criticised for ignoring the need for flexibility and variability when counselling people with different needs and motivations (125). Ogden warns that if we remove this flexibility in counselling, we are no longer professionals but merely technicians. Others argue that what separates an excellent professional from a good one is the flexibility, intelligence and ability to use all the knowledge in counselling, and that

the COM-B system is among the best tools today to guide design in real world interventions (126).

Researchers promoting MI have criticised Michie and colleagues' taxonomy for focusing exclusively on the content of interventions and ignoring the counsellors' manner of presenting the BCTs (interpersonal, relational style or therapeutic alliance). The MI counsellor`s use of language, e.g. avoiding controlling language, adopting a non-confrontational and non-judgemental approach, illustrates how the interpersonal style may interact with the BCTs in the therapeutic alliance towards behaviour change (127). Compared to SDT, the COM-B system does not emphasise the type of motivation and the importance of the internalisation of positive motivation in order to explain the maintenance of change in behaviour. It is important to also acknowledge that the effectiveness of a BCT is a result of target behaviour, population, setting, mode of delivery, and interaction with other BCTs (126). The COM-B system illustrates the importance of opportunity, pointing towards possible barriers for change inherent in the environment. Capability, such as competence, and motivation may not always be enough, e.g. when experiencing low income, being a single parent or lack of social support.

1.7 Summary: the evidence gap

The Norwegian HLCs are a new service in primary health care. The interventions share similarities with the brief advice on physical activity given by GPs or other health professionals in primary care, and disease specific rehabilitation programmes that take place in specialised care, such as for cardiac or pulmonary disease. Whereas the evidence base for brief advice and rehabilitation is strong (128), the evidence base for the ERSs or similar behaviour change interventions is uncertain or modest, at least in the longer term (14, 47, 58, 59).

The Norwegian Directorate presents the HLCs as a success story with a wide range of beneficial results (8). However, the recommendations for design and implementation

of interventions do not include a guideline for evidence-based practice in counselling for behaviour change, as have been developed in other countries (52, 69-71). This fact may limit the scaling-up of good practice and meaningful evaluation to inform policy. Accordingly, there is a need for a synthesis of evidence for the design and implementation of interventions similar to those experienced to date by participants at the HLCs.

Several reviews have identified successful intervention components for different groups of people. Dombrowski and colleagues' review of effective BCTs for obese adults limited the inclusion criteria to participants with additional risks of morbidity or co-morbidity (93). However, the HLCs also include self-referred, inactive, sedentary individuals, irrespective of identified risk of morbidity. In addition, Dombrowski and colleagues included studies published up until 2008, used a taxonomy with only 26 BCTs, and did not identify any BCTs associated with change in physical activity. Until 2013, no reviews used the recent and more comprehensive BCTTv1 (91). All the reviews using the different taxonomies identified associations between BCTs and outcome results at one single time point, namely post intervention. None of these have, to our knowledge, investigated the association at a later follow-up date.

By 2008, only a few of the studies included in the previously mentioned reviews used MI as a counselling method. We hypothesised that counselling methods associated with internalising of motivation would lead to persistence of behaviour change over time, and that effective methods associated with short and long-term results might differ. Consequently, we asked if there was a difference between BCTs or other study characteristics associated with short or long-term effects. To answer this question, our plan was to undertake a systematic review to explore the effect of different intervention characteristics at short and long-term follow-up. We judged this evidence to be important in the design and implementation of HLC interventions, and

an important contribution towards building a logic model that could explain the causal assumption underpinning the results.

The HLCs are still under development and focus mainly on physical activity, healthy eating and tobacco cessation. However, the government plans to include patient education and self-management programs targeting the most common NCDs and more complex, long-term health problems in the future (129). There is a need to evaluate the HLC interventions' effects as part of public policy and practice to combat NCDs, and as a means to reduce social health inequalities. Based on the critique of earlier studies, there is a need for an RCT with follow-up data, and the objectively measured core outcome of physical activity in order to establish causality. To do this, an RCT with a longitudinal follow-up was planned to evaluate the short and long-term effect on physical activity, self-perceived health and well-being, self-reported diet and eating behaviour, tobacco use, sleep, and concerns about body image.

2. Aims and research questions

The aim of this thesis is to present theoretical frameworks and models for the development of behaviour change interventions (Chapter 1.6), to produce new knowledge about effective interventions for participants similar to those attending the HLCs (Study 1, Paper I), and to evaluate the HLCs' intervention effect (Study 2 The Norwegian Healthy Life Study, Papers II, III and IV)) (See Figure 6).

2.1 Study 1

The aims of the study were to synthesise the evidence of behaviour change interventions to improve physical activity and healthy eating for overweight and obese adults at short and long-term follow-up, and to use meta-regression analyses to examine what factors could explain the heterogeneity across studies (Paper 1). Our research questions:

- Were the interventions effective at short and long-term?
- Did the intervention effects at short or long-term vary according to BCTs and other study characteristics?

2.2 Study 2

The specific aims of the papers were:

1) To present the study protocol for The Norwegian Healthy Life Study, a pragmatic RCT with a longitudinal follow-up to assess the short and long-term effects of the HLCs` behaviour change interventions for adults on physical activity, self-perceived health and well-being, self-reported diet and eating behaviour, tobacco use, sleep, and concerns about body image (Paper II).

2) To study the characteristics of the participants at baseline (Paper III). Our research questions were:

- What were the characteristics of the participants?
- What reasons did they give for attending HLCs?
- How much time did they spend being physically active at a moderate to vigorous intensity level at baseline?
- Were socio-demographic characteristics, motivation, self-efficacy, and social support for physical activity associated with MVPA at baseline?

3) To evaluate the effect of the HLC interventions on MVPA after six months, compared to waiting list controls (Paper IV). Our research questions were:

- What was the intervention effect on MVPA, when compared to the control group?
- Did socioeconomic status, motivation or other characteristics mediate change in MVPA six months after baseline, and did level of education and MVPA at baseline modify the effect?

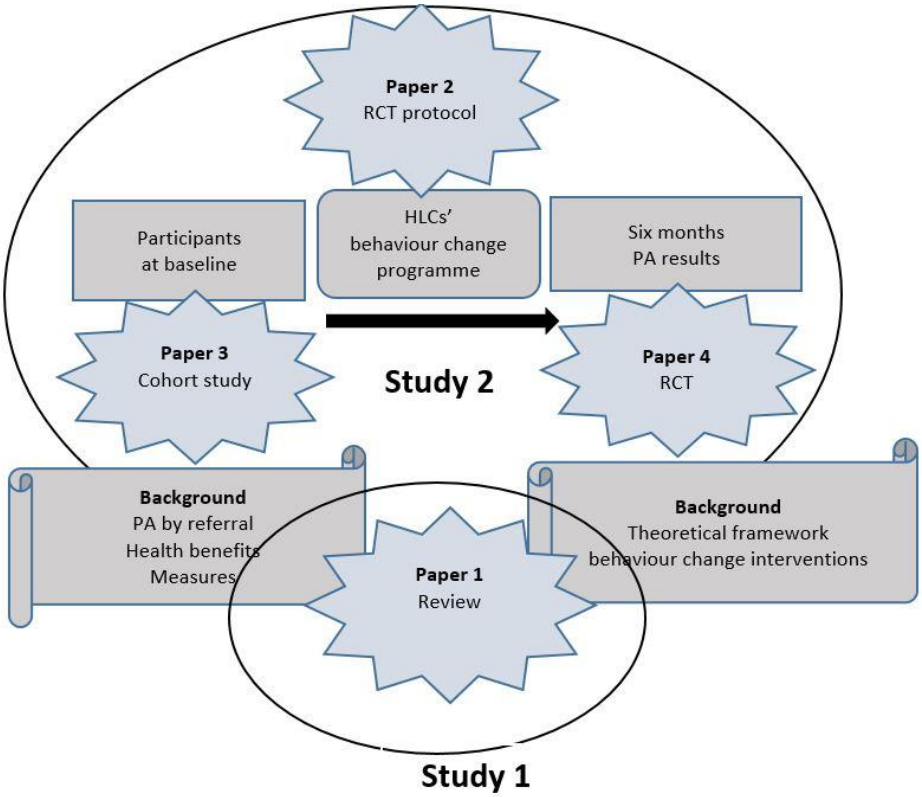

Figure 7 Illustrating the content of thesis; Study 1 and 2 with papers.

3. Design, material and methods

The thesis includes two studies and four papers. Study 1 is a systematic review and meta-regression analyses of physical activity and healthy eating interventions for adults (Paper I). Study 2 presents how the Norwegian Healthy Life Study aims to evaluate the effect of HLCs' behaviour change interventions (Paper II). Paper III presents results from the baseline study, and Paper IV presents the results of the interventions on the primary outcome of MVPA at six months when compared with a control group.

3.1 Study 1 The systematic review

3.1.1 Design

We wanted to conduct a systematic review and meta-analyses of physical activity and healthy eating interventions and used meta-regression analyses to examine if BCTs and other intervention characteristics were associated with effect on PA and healthy eating. We intended to include a study population similar to the participants at the HLCs: obese and in need of diet and PA interventions to improve health. Being obese and middle aged are associated with several obesity-related diseases. We did not ask for additional risks of morbidity or co-morbidity in the inclusion criteria.

3.1.2 Protocol and registration

The review was preregistered at International prospective register of systematic reviews (PROSPERO) (CRD 42015020624) and reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses, the PRISMA checklist (130). (Research protocol and research strategy, se Appendix.)

3.1.3 Eligibility criteria

The inclusion criteria were peer-reviewed RCTs and cluster randomised trials with ≥ 12 weeks' duration from January 2007 to October 2014, for adults (mean age ≥ 40 years, mean BMI ≥ 30 kg/m^2). Primary outcomes had to include measures for change in healthy diet or physical activity by post-intervention and later follow-up compared to a control group, such as usual care, waiting list control or a less intensive intervention. There were no restrictions on setting.

3.1.4 Information sources

We researched the electronic databases MEDLINE, PsycInfo and EMBASE for articles published in peer-reviewed journals from January 2007 to April 2013. The search was updated once to include articles published up to October 2014. The reference lists of relevant reviews identified in the search process were also screened (14, 119, 120, 131-138), in addition to four prominent journals in the field of health-related behaviour research.

3.1.5 Search strategy

The search strategy was preregistered at PROSPERO (CRD 42015020624). We used a search strategy from a previous systematic review with a few adjustments (93). "Motiv* interview*" was added to the concept "psychological interventions", the search term "healthy eating" was added to "diet", and "physical activity" or "walking" were added to the term "exercise".

3.1.6 Study selection

We performed relevance checks on the titles of 6283 articles using a standardised form developed for this study which included the following check points: RCTs or cluster randomised trials, intervention duration ≥ 12 weeks, a counselling strategy, from January 2007, mean age ≥ 40 years, mean BMI ≥ 30 kg/m^2, a diet and/or physical activity outcome. Title or publication information could lead to exclusion,

e.g. if the title mentioned prospective study, tobacco cessation, adolescence, or the paper was published before 2007. Two tests identified 94% and 90% inter-rater agreement between two reviewers across the first 100 titles. After these tests, one researcher identified the rest of the titles for inclusion. After checking all titles, the two reviewers independently screened 584 abstracts of titles that were not excluded in the same manner. This resulted in an 85% agreement about whether to 1) include; 2) exclude, or 3) carry out a full text evaluation.

3.1.7 Data collection process and data items

Two researchers cooperated in collecting the outcome results. If a study targeted both diet and physical activity, we collected the data separately. The effect measures were reported in six different ways: 1) baseline and follow-up data per group; 2) data of change within each group; 3) follow-up status per group; 4) estimates of difference of change between groups; 5) numbers and fractions of participants who reached behaviour goals at follow-up, and 6) standardised effect size between groups (e.g. Cohen's d).

Where the studies reported more than one outcome per behavioural domain, we extracted outcomes in the following order of priority: 1) measure defined as the primary outcome; 2) objective measurement, or 3) the most comprehensive measurement (e.g. total fat consumption was preferred over saturated fat).

The duration of the interventions, frequency, and time of data collection varied across studies. Baseline, six months and 12 months were the most common time points, and we extracted results at the following time points if available: 1) at baseline; 2) post-intervention ($\leq$ six months after baseline) to identify initial changes in behaviour, and 3) at last follow-up ($\geq$ 12 months after baseline) to identify maintenance of change.

We used two data collection forms based on the Template for Intervention Description and Replication (TIDieR) checklist and guide to extract the study and intervention characteristics of the included studies (139). One researcher collected the

data, which was later checked by the second researcher (Paper 1, Additional File 2, Included studies, and Additional File 3, Intervention characteristics.) Two researchers independently identified BCTs present in the intervention and absent in the control condition. We used a standardised extraction form developed for this study to identify target population, target behaviour, outcome behaviour, BCTs present in intervention group, and BCTs present in the control condition (if any), based on definitions of 93 BCTs in the BCTTv1 taxonomy (91). (Paper 1, Additional File 5 for identified BCTs per study). In addition, we identified the total number of different BCTs (sum of both intervention arms). Disagreement was resolved through discussion between two coders, or, in two cases, by consulting the third coder. The mean kappa inter-rater agreement coefficient was 0.46 (range: 0.08 to 0.76) with an overall agreement between coders of 82% as to whether a BCT was present or not (range: 62-93%).

3.1.8 Risk of bias in individual studies

Two researchers independently assessed risk of under or overestimating the intervention effects using the Cochrane risk of bias form (140). We deemed outcomes measured with objective methods, such as from an accelerometer, to have a low risk of bias due to the lack of blinding of outcome assessment. We judged self-reported diet measurements to be at high risk of performance bias. The only exception was vitamin C in blood in one study (Paper 1, Additional File 4, Risk of bias).

3.1.9 Statistical analysis

Statistical approaches were used to re-express odds ratios (from dichotomous data) as standardised mean differences allowing dichotomous and continuous data to be pooled together (Hedges'$g = (m_i-m_c)/sd_{ic}$). (Paper 1, Additional File 1, Computation of standardised mean differences). We performed meta-analysis separately for short and long-term effects of interventions. Diet and physical activity outcomes were judged to be similar and analysed together. We applied meta-regression analyses to investigate potential predictors such as bias, BCTs, and several other study

characteristics as possible sources of heterogeneity. We estimated pooled overall effect sizes (ES) with 95% confidence intervals (CIs) and reported I^2 with significance probability (p-value) as an index of heterogeneity (Paper 1, Additional Files 4 and 5).

3.2 Study 2 The Norwegian Healthy Life study

3.2.1 Design

The Norwegian Healthy Life Study is a pragmatic RCT with a longitudinal follow-up (24 months after baseline) to assess the effect of interventions on physical activity, self-reported health and wellbeing, diet and eating behaviour, tobacco use, sleep, and body image concerns, and to explore factors that mediate these effects. Participants were included if they were deemed eligible for service by the HLCs, were aged ≥ 18 years, and could participate in a group intervention held in the Norwegian language.

The thesis includes the study protocol (Paper II), and the cross-sectional study of the HLC participants before they were randomised to receive the intervention or the control (wait six months for the intervention) (Paper III). Paper IV presents the results of the intervention on MVPA and time spent being sedentary six months after baseline, when compared to controls. We excluded participants with severe mental illness, learning disability, or those who attended only for a tobacco cessation intervention.

3.2.2 Setting

The research group invited a convenient sample of 12 HLCs from their surrounding area on the South and West coasts of Norway to participate in the research. Four declined, one due to other research commitments. The eight remaining municipalities represent 630,000 inhabitants from both rural and urban areas (6000-270 000). One HLC served three municipalities, leaving six HLCs in total.

3.2.3 Study period and population

The HLCs invited 351 people to take part in the research study from June 2014 to September 2015. They were referred to the HLCs by their GPs, by other professionals in the municipalities, or they came to the HLCs on their own initiative. Of the 351 invited, 118 people agreed to participate (35%) from June to September 2015. The randomisation, based on a random number list, aimed to provide approximately equal distribution of participants in the intervention and the control group at each HLC. A project manager at the university drew a card from numbered, sealed and opaque envelopes and assigned participants to either intervention or waiting list (control). This procedure ensured concealment of the sequence to the HLCs enrolling the participants, and concealed identity and patient characteristics to the researchers. After the inclusion visit and registration of baseline data, we randomised 57 participants to the intervention group and 61 to the control group. The main reason people gave for refusing to be included in the research study was the risk of having to wait six months for the intervention. We asked the control group to live their lives as normal and gave no restrictions with respect to behaviour change.

3.2.4 Data collection

For the intervention group, data was collected at baseline, after six months (post-intervention), and 24 months after baseline. The controls were measured at baseline, six months after baseline (pre-intervention), 12 months after baseline (post-intervention), and finally, at 24 months from baseline. The survey was administrated using an online survey management system (SurveyXact TM; Rambøll Management Consulting, Oslo, Norway), and completed at the HLCs. We tested the survey on three participants from different HLCs. The questions were clear and understood by our testers and the participants finished the survey within 30 minutes.

HLC personnel measured each participant's weight, height and waist circumference (light clothing, no shoes). They measured waist circumference at the level of the

umbilicus. We obtained the following data at baseline: biomedical and socio-economic data, childhood experience of parental acceptance, and reasons for attending an HLC. Childhood experience of parental acceptance and rejection has been linked to adults' behavioural and emotional adjustment (141). We added a single self-assessment item measuring the experience of quality in childhood: "I experienced respect and appreciation in my childhood" (Likert scale 1-7) with response categories from "Strongly disagree" to "Strongly agree". The item is similar to a question associated with multi-morbidity and allostatic load in a study of the Norwegian population (142). A single item self-esteem scale (SISE) ("I have high self-esteem") assessed global self-esteem with response categories (Likert scale 1-7) from "I do not agree at all" to "I agree". The scale was used previously in research on an adult population (143). Measures of socioeconomic status (SES) were defined as level of education (five item scale) and gross family income (seven item scale from NOK < 201 000 to > 850 000). At post-intervention and follow-up, we asked participants about the duration of their contact with the HLC and what types of intervention they had attended.

Objective methods to measure physical activity

We wanted to study the effect of interventions on physical activity in inactive, overweight or obese adults and considered a monitor sensor to be the best assessment method. The primary outcome was MVPA measured with SenseWear Armband Mini; BodyMedia Inc., Pittsburgh, Pennsylvania, USA) (SWA).

In accordance with the instructions from the manufacturer, the HLCs instructed the participants to wear the SWA 24 hours per day for seven days, except for showering or water-based activities. We entered participant's gender, age, weight, and height into the SWA via a USB - PC connection prior to each new monitoring. The algorithms in the producer's software (Version 7.0) transforms SWA files of acceleration, heat flow and other parameters into output measurements, such as total EE, activity duration, steps, and off/on body time. The analyses included data from participants with ≥ four days' measurements at baseline, and three days'

measurements at post-intervention. Valid days covered at least 19.2 hours during a given day, or 80 % of a 24-hour time period. The cut-off point for the activity intensity categories were: sedentary behaviour 1 - 1.4 METs; light physical activity 1.5 - 2.9 METs; moderate physical activity 3 - 5.9 METs, and vigorous intensity ≥ 6 METs (39, 40).

Secondary measures

Time spent in sedentary behaviour, self-reported physical activity, self-reported diet and eating behaviour, self-reported health and wellbeing, tobacco use, sleep, and concerns with body image were secondary outcomes.

The survey included two questions about exercise similar to a Norwegian population survey (144): "In general, for how long are you physically active each day". The possible answers were: "Less than 10 minutes each day", "11 - 20 minutes each day", "21 - 40 minutes each day", "41 - 60 minutes each day", or "More than 60 minutes each day". The other question "How hard do you exercise?" had the response categories: "I take it easy without getting breathless and sweaty", "I get a little breathless and sweaty", "I definitely get breathless and sweaty", or "I am almost totally exhausted". The questions were tested and compared to biological markers in a Norwegian study (145). The survey also included two questions measuring the participants' knowledge of places where they can be physically active or do some exercise: "I know one or more places where I can be physically active or exercise" and "I attend one or more of these places to be physically active or exercise". The response categories (Likert scale 1 - 4) went from "I do not agree at all" to "I agree".

The survey also measured habitual diet, beverage consumption, meal pattern and eating behaviour. We used questions measuring meal frequency, meal composition, and beverages previously used in Norwegian Health Surveys (146). We assessed meal frequency by asking, "How often do you have breakfast each week?". The question was repeated for lunch, dinner, and supper (Likert scale 1 - 8). Response categories ranged from "never", or "seldom", to seven days a week (7). Consumption

of food was measured by questions, such as “How often do you eat fruit and berries/vegetables/ candy/salty snacks/cake, cookie, pastries, fast food/nuts/high fat dairy products/low-fat dairy products/ fish/ red meat /white meat/ oils?” We measured beverages with the questions “How often do you drink water/ regular soft drinks/ diet soft drinks/ fruit juices?”. The participants could answer each question “never”, “seldom”, or report frequency per day, or per week. The study emphasised diet items similar to the Mediterranean diet, which is associated with reduced morbidity in primary and secondary outcomes studies (147, 148). The Mediterranean diet is characterised by high consumption of olive oil, fruit, vegetables, non-refined bread and cereals, potatoes, legumes and nuts, fish and poultry, full-fat dairy products, and alcohol (149).

In order to measure dysfunctional eating patterns, the survey included The Three Factor Eating Questionnaire. The 18 items cover three behaviour scales (TFEQ-18): Emotional eating (three items) (the tendency to overeat in relation to negative emotions); cognitive restraint (six items) (the tendency to restrict one’s food intake instead of using physiological cues, hunger, or satiety as regulators of food intake), and uncontrolled eating (nine items) (the tendency to overeat and to lose control over eating). The scales range from 0 - 100, and higher scores indicate more restraint, uncontrolled, or emotional eating. TFEQ is tested and validated in studies of adults of different weight categories in Scandinavia (150-152). Use of tobacco was measured by one question “Do you smoke or use snuff?”. Response categories were “Yes, I smoke daily”, “Yes, I smoke, but not daily”, “Yes, I snuff daily”, “Yes, I snuff but not daily”, or “No”.

The Impact of Weight on Quality of Life-Lite Questionnaire (IWQOL-Lite) is an obesity-specific quality of life measure (153). The 31 items version covers five domains: physical functioning, self-esteem, sexual life, public distress, and work, and it has been tested on obese adults in Norway (154). The sub scores are transformed into scales from 0 - 100. High scores indicate the high impact of obesity on quality of life. We used nine of the eleven items that cover physical function, and four of the

seven items covering self-esteem (Likert scale 1 – 5). The response categories were "never right", "seldom", "sometimes right", "usually right" to "always right".

Subjective well-being or life evaluation was assessed using the single item Cantril's ladder, where individuals are asked to place themselves on an 11-step ladder (155). The worst possible life equals the first step (0) and the top step represents the best possible life (10). Well-being has also been associated with self-esteem and subjective vitality (156). Vitality is associated with fulfilment of the three basic psychological needs according to SDT (157). Subjective vitality was measured with three of seven items from the Subjective Vitality Scale (Likert scale 1-7) with response categories from "Strongly disagree" to "Strongly agree", previously used in a survey of older adults in Norway (156, 158). Self-rated health was measured by a single item question "How is your overall health at the moment?". Response categories were "Very good", "Good", "Neither good nor bad", "Fair" and "Bad". The question was previously used in a Norwegian population study (159).

Sleep patterns were measured with a seven day, five item, structured log-book (160). The participants wrote down the answers to these questions every morning: "When did you go to bed?", "When did you turn off the lights?", "How long, from the time you turned off the lights, before you went to sleep?", "If you were awake during the night, how long did the period(s) last altogether?", "When did you wake up without going to sleep again?", and "When did you get out of bed?".

In order to measure the effects of interventions on subjective body experience and problems, we included three questions to measure concerns about body image, previously used in WHO's cross-national survey, including Norway, for school-aged children (161). The questions were "What do you think about your body?". The participants could choose one of these answers: "much too thin/ a bit too thin/ about the right size/ a bit too fat/ much too fat". Similarly, we asked participants: "Are you trying to lose weight?" with response categories: "No, because my weight is fine / No, but I need to lose weight/ No, I need to put on some weight", or "Yes".

We also included the Body Attitude Test (BAT) (162). BAT measures four dimensions: negative appreciation of body size; lack of familiarity with one's own body; general dissatisfaction, and a rest factor. BAT has been shown to differentiate between types of eating disorder and is tested on adults in Norway (163).We included the dimension lack of familiarity with one's own body (7 items) (Likert scale 1-5), which includes statements like "I feel good in my body" and "I feel tense in my body". Two positive statements must be turned to negative scores before analysis. Higher scores indicate greater problems and the maximum score is 100. Response categories were from "never" to "always". Cronbach`s alpha for the mean was 0.86 in this study at baseline.

Predictors (Explanatory variables)

In Study 1, we identified that the use of an autonomous supportive method of counselling was associated with intervention success in both the short and the long-term. SDT relevant questionnaires measuring types of motivation and perceived autonomy support from counsellors were therefore included in Study 2, together with other possible mechanisms taken from the literature through which an intervention might achieve the effects: self-efficacy for physical activity, social support for physical activity, social support in general, and defiance.

Self-efficacy for physical activity was measured using a questionnaire previously used in Norwegian studies (8 items) (30). We asked the participants to score how confident they were in their ability to be physically active in situations representing three practical and five psychological barriers. The response categories (Likert 1-7) were from "not at all confident" to "extremely confident". Cronbach`s alpha for the mean was 0.93 in this study at baseline. Social support for physical activity from friends and family was measured using a six item scale previously used in Norwegian surveys (20, 164). Cronbach`s alpha for the mean was 0.85 in this study at baseline.

The Oslo-3 Social Support Scale (OSS-3) is a three item questionnaire that measures the number of close confidants, sense of concern and interest from other people, and

relationship with neighbours. The response categories on a Likert scale 1- 5 add up to a sum score. Lower scores indicate low social support. OSS-3 has been tested across several countries and predicts psychological distress, especially in relation to somatic health problems (165, 166). Cronbach`s alpha for the mean was 0.73 in this study at baseline.

SDT focuses on people's motivations or reasons for engaging in activities, or for non-engagement. The survey included two questionnaires to measure SDT relevant mediators and outcomes: The Treatment Self-Regulation Questionnaire (TSRQ) and The Health Care Climate Questionnaire (HCCQ). TSRQ measures the reasons why people want to change an unhealthy behaviour, or to continue a changed behaviour (167). The scale identifies three types of regulation: autonomous regulation (six items); controlled regulation (six items), and amotivation (not motivated for change) (three items) rated on a Likert scale 1 - 7 from "never" to "always". The items constitute the composite score of each type of regulation. TSRQ is validated in several studies across different health behaviours (167, 168), including participants with CHD in a rehabilitation program in Norway (169). Cronbach`s alpha for autonomous, controlled regulation and amotivation was 0.81, 0.73 and 0.56 respectively. The HCCQ measures the participants' perceived autonomy support from their counsellor. We used four of the six items version. The response scales were on a Likert scale (1 - 7) from "strongly disagree" to "strongly agree", and higher scores represented more support for autonomy. The HCCQ has been tested and found to be valid in several intervention studies targeting multiple health domains, including a study on physical activity in Norway (170-172).

Defiance can be defined as a tendency to oppose or reject advice from people in authority, e.g. a counsellor, and it represents an additional motivational force. We applied four items from research on parental styles and changed the wording to fit a counselling session for behaviour change. (173, 174). Cronbach`s alpha for the mean was 0.89 at baseline.

3.2.5 Statistical analysis

In Paper III, we grouped education into three categories used by Statistics Norway (2017): upper-secondary school or below; higher education short < 4 years, and higher education long ≥ 4 years. In Paper IV, we divided the education variable into three approximately equal sized categories of participants: 1) Low: upper-secondary school and below; 2) Middle: upper-secondary school with general studies, and 3) High: University college and/or University. We also constructed a composite score of reasons for attending the HLC: 1) mental or musculoskeletal challenges, and 2) chronic somatic disease (diabetes, high blood pressure, cardiovascular or lung disease).

Mean gross family income in the study was NOK 550 000, mean age was 48 years, and 40% of the participants were single. According to Statistics Norway (2017), income after tax for single adults aged 45 to 66 is NOK 273 000. In Paper IV, we therefore split the participants' gross income into two groups NOK ≤ 400 000 and NOK > 401 000.

We presented the participants by descriptive statistics of each potential predictive value and physical activity intensity level. We applied gender, age, education, gross family income, working status, childhood experience of respect, self-esteem, self-rated health, types of motivation, defiance, self-efficacy and social support for physical activity, and reasons for attending the HLC as predictors in Papers III and IV. To compare the different variables, we reported results for each predictor as the standardised regression coefficients (b) with the p-value from the F-test. We explored if the predictors could explain motivational factors with autonomous regulation, controlled regulation, self-efficacy, and social support for physical activity as response categories in linear regression analyses. Finally, in Paper III, we investigated the predictors' association with MVPA at baseline using simple and multiple linear regression analyses. We defined adherence to Norwegian

recommendations for moderate physical activity as the percentage of participants accumulating ≥ 0.5 hours of MVPA per day multiplied by 7 days a week.

In Paper IV, we used multiple logistic regression analyses to identify the participants' risk of dropping out of the interventions according to predictors and MVPA at baseline. We identified the six months' intervention effect using linear regression analysis of MVPA and sedentary time, adjusting for baseline values and group allocation. In order to explore how different predictors affected change in MVPA, we used simple linear regression analyses to explore how gender, age, intervention group, and MVPA at baseline affected MVPA at post-intervention. Thereafter, we applied multiple linear regression analyses for each of the other predictors, adjusting for the above-mentioned predictors. Finally, we entered gender, age, intervention group, and MVPA at baseline and the significant predictors in the same full model, exploring the impact of each variable adjusted for the associations between them. We also performed interaction analyses to explore differences in effect across MVPA at baseline by entering an interaction term between MVPA and intervention group. Likewise, we entered interaction terms between level of education (low and middle compared with high education) and intervention group. We used SPSS (IBM Statistical Package for the Social Sciences version 24) for all statistical analyses, and a p-value ≤ 0.05 was accepted as significant.

Based on an estimate from a cross-sectional study, we presumed that people who attended HLCs were somewhat more sedentary and were possibly harbouring greater variation than the general Norwegian population (175). The power calculations showed that we needed 51 participants in each group, presupposing that we wanted to rule out a 10 minute difference in daily MVPA with power 0.8 when the groups reached post-intervention levels of MVPA, corresponding to 20 (SD 15) and 30 (SD 20) minutes of daily MVPA. To account for drop out, we recruited 118 participants, 57 in the intervention group and 61 in the control group.

3.2.6 Ethical approval

The Regional Committee for Medical and Health Research Ethics approved the experimental protocol. Informed consent was obtained from each participant prior to participation in the study (no 2013/1291).

4. Results

4.1 Paper I

The systematic review synthesised the evidence for physical activity and healthy eating interventions for overweight and obese adults. The search strategy identified interventions similar to the HLCs' model, and targeted participants similar to the HLC participants, e.g. RCTs or cluster RCTs of intervention duration ≥ 12 weeks with a behaviour change strategy, participants' mean BMI ≥ 30 kg/m^2 and mean age ≥ 40 years (Figure 8). The meta-analyses identified the intervention effects at short (≤ six months) and long- term (≥ 12 months), and meta-regression analyses explored the association between successful interventions, BCTs and other intervention characteristics. The 48 RCTs included in the review resulted in 82 diet and physical activity outcome reports in total. The 50 short-term reports had an effect size (ES) = 0.37 with 95 % CI: 0.26 to 0.48, and I^2 = 71.3 %, $p < 0.001$. The intervention effect was reduced by time, and 32 long-term reports had an ES = 0.24 with 95 % CI: 0.15 to 0.33, and I^2 = 59.4 %, $p < 0.001$ (Table 1). At both short and long-term, using the BCTs *goal setting* and *self-monitoring of behaviour* were associated with a positive intervention effect, along with using more BCTs exclusively in the intervention group. In addition, maintenance of change in long-term reports was associated with either using a patient-centred and autonomy supportive approach in counselling, or the BCTs *goal setting of outcome*, receiving *feedback on outcome of behaviour*, setting *graded tasks*, and *adding objects to the environment to* support behaviour change.

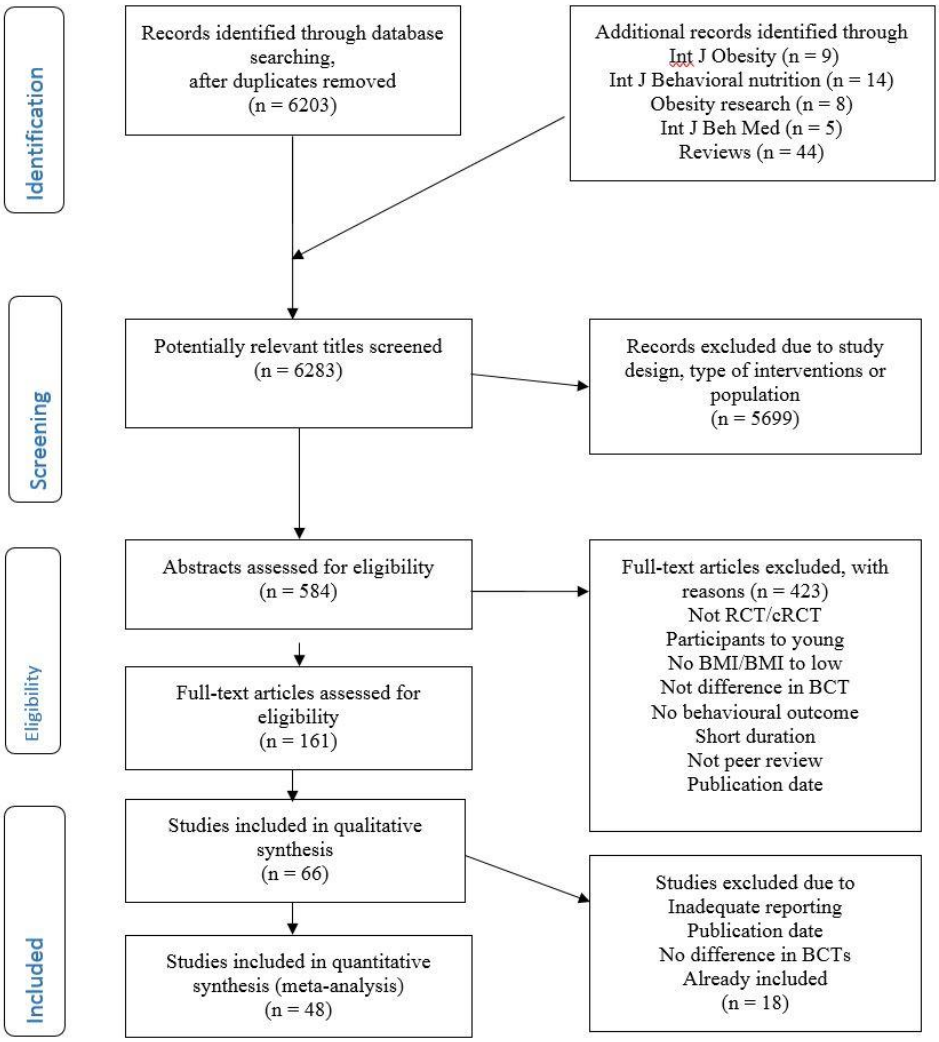

Figure 8 PRISMA Flow Diagram for the inclusion of studies in a systematic review of physical activity and healthy eating interventions for overweight and obese adults from January 2007 to October 2014.

A total of 58.8% of inter-study variation in the short-term was explained by the BCT *goal setting of behaviour* (b = 0.440; 95 % CI: 0.225 to 0.655) and the presence of

reporting bias (b = 0.530; 95 % CI: 0.257 to 1.034). There was however, a strong inter-correlation between *goal setting of behaviour* (named BCT 1.1 in the BCTTv1) and *self-monitoring of behaviour* (BCT 2.3). When we substituted the BCT 1.1 with 2.3 in the final regression analysis, *self-monitoring of behaviour* was also associated with effect in the short-term (b = 0.355 with 95 % CI: 0.128 to 0.582), but this model only explained 46.7% of the variance. At long-term, all of the variation in effects (100%) between studies was explained by the BCTs receiving *feedback on the outcome of behaviour* and *goal setting of behaviour,* and using an autonomy supportive and person-centred method in counselling, e.g. as seen in MI and SDT-based interventions. There was a strong inter-correlation between the BCTs *feedback on outcome of behaviour* (named BCT 2.7) and *goalsetting of outcome* (BCT 1.3). We substituted BCT 1.1 with BCT 2.3 and the BCT 2.7 with BCT 1.3 in the final regression analysis. *Goalsetting of outcome* (BCT 1.3) was still associated with long-term intervention effect (b = 0.149; 95 % CI: 0.005 to 0.292), but the BCT *self-monitoring of behaviour* only reached borderline significance (p = 0.059). In addition, this model predicted 100% of the variance.

Table 1 Summary effects of behaviour change of interventions in a meta-analysis of 48 RCTs 2007-2014.

Table1 Summary effects of behaviour change of interventions in a meta-analysis of 48 RCTs 2007-2014

Time	Short term	Long term	Short + long term
Response measure	**ES 95% CI**	**ES 95% CI**	**ES 95% CI**
Physical activity	0.36 (0.24,0.47)	0.25 (0.13,0.38)	0.31 (0.23,0.40)
35 trials	30 reports	17 reports	47 reports
Diet	0.41 (0.20,0.62)	0.19 (0.07,0.31)	0.29 (0.16,0.42)
26 trials	20 reports	15 reports	35 reports
PA + Diet	0.37 (0.26,0.48)	0.24 (0.15,0.33)	
61 trials	50 reports	32 reports	82 reports

We found no evidence that the mode of the intervention delivery (individual, group or web based, or a mix of these) affected the results. Nor could the provider's profession or competence, treatment setting, or the duration of the intervention explain the

results. The interventions' success showed no association with studies targeting change in one versus two domains. The results of this review did not support the claim that theory-based interventions are more effective in changing diet or physical activity than interventions that are not based on theory.

4.2 Paper II

The paper presents the rationale, design and methods for a six-month pragmatic RCT with a longitudinal cohort study 24 months after baseline. The study aimed to evaluate the effect of interventions from Norwegian HLCs' on physical activity, self-reported health and wellbeing, diet and eating behaviour, tobacco use, sleep, concerns with body image, and to explore the factors that mediate these effects. The participants were from six HLCs and they were recruited from June 2014 to September 2017. They were ≥ 18 years old, at risk of developing, or already had, an NCD, and were randomised to behaviour change interventions or a waiting list. Exclusion criteria were severe mental health problems, general learning disability, or being unable to participate in a group-based intervention in the Norwegian language.

The Directorate of Health gave some basic recommendations for implementation of the HLC model: a referral from a GP, or from another health care/public provider, or self-referral to group-based behavioural change interventions for 12 weeks with an individual counselling session at entry and exit based on MI. The group-based physical activity interventions consisted of elements from aerobic training (e.g. Nordic walking), light strength training, stretching, and games, which are encouraged twice a week. The participants are offered a group-based course to promote healthy eating (10 hours), and smoking cessation if they want to stop smoking. Group-based interventions provide opportunities for social support and encouragement among participants in the same situation.

The paper discussed how an RCT may evaluate a complex intervention already in routine practice in primary health care. Based on an understanding of local adaptation

of the HLC model across eight municipalities, contextual diversity and available competence, we designed an RCT where the interventions were standardised by purpose (aims, functions, methods), and not by the actual active components. We believed that interventions tailored to local conditions might provide more convincing evidence of effect, and that generation of knowledge may come from local practitioners as well as from the researchers. The results of this trial may influence future public health policy and the design and implementation of HLC interventions in primary health care.

4.3 Paper III

This paper presents 118 participants recruited from six HLCs in eight municipalities (Kristiansand, Sola, Sandnes, Time, Bergen, Fjell, Sund, and Øygarden). Only 34% of those invited agreed to be randomised making selection bias a serious threat to the external validity of the study (Figure 9).

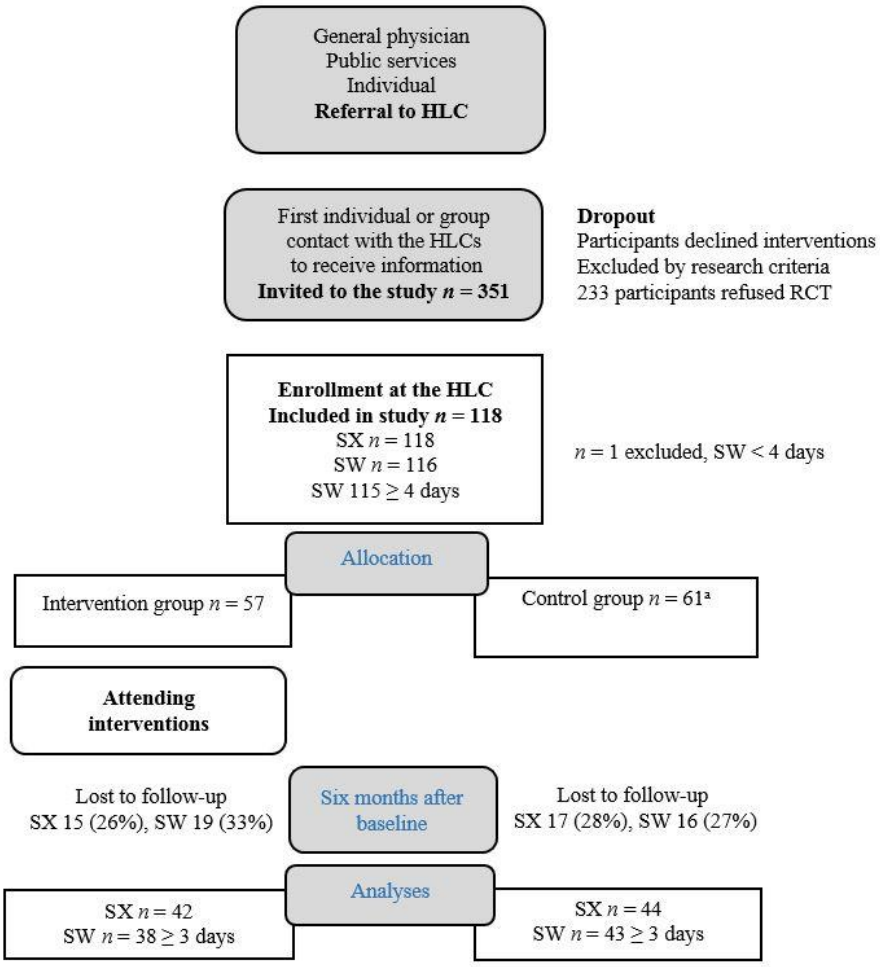

Figure 9 Participants in the Norwegian Healthy Life Study recruited from June 2014 to September 2015. Flow chart of referral, uptake, and attendance. SX = SurveyXact online survey; SW = SenseWear physical activity monitor. [a]SW *n* = 59.

The majority of participants were women (77%), with mean (SD) age 48.6 (13.4) years, and BMI 34.0 (5.8) kg/m^2. Mean gross family income was 590 000 NOK (€61.000), and 55% had upper-secondary school or less as their highest level of

education. The most frequently cited reasons for attendance were: being overweight, wanting to increase physical activity or improve diet, and having musculoskeletal or mental challenges. Before starting the behaviour change programme, participants reported high levels of autonomous motivation for change, and 79% achieved 150 minutes of MVPA per week measured with SWA (no bouts) (Table 2).

Two out of five reported low self-esteem and 33% had experienced low respect and appreciation in childhood. These characteristics of disadvantage were associated with low self-efficacy, and a lack of social support for physical activity, both important predictors for change. Low self-efficacy and low social support for physical activity were also associated with poor self-reported health. We found no association between the level of physical activity and education, type of motivation, or self-efficacy, but having low self-esteem and psychological problems were associated with being more sedentary at baseline. High levels of autonomous motivation for change are beneficial, but the behaviour change interventions need to address participants with poor health, impaired self-efficacy, and lack of social support. An RCT will reveal if the interventions increase MVPA further, and if health inequalities narrow or widen across groups.

Table 2 Descriptive baseline statistics of 118 participants in the Norwegian Healthy Life Study RCT recruited from June 2014 to September 2015 for total and according to intervention and waiting list (control) groups.

Variable (scale) Category	Total N = 118 (100%)		Intervention group n = 57 (48.3%)		Control group n = 61 (51.7%)	
Female, *n (%)*	91	(77.1)	45	(78.9)	46	(75.4)
Age in years, *mean (SD)*	48.6	(13.4)	47.7	(13.3)	49.4	(13.5)
BMI kg/m², *mean (SD)*	34.0	(5.8)	33.8	(6.2)	34.1	(5.4)
≥ 30 kg/m², *n (%)*	88	(74.6)	40	(70.2)	48	(78.7)
Smokes daily, *n (%)*	18	(15.4)	9	(16.1)	9	(14.8)
Self-rated health (1-5)						
Very good or good health, (> 3), *n (%)*	18	(15.5)	9	(50.0)	9	(50.0)
Bad or fairly bad health (< 3), *n (%)*	65	(56.0)	34	(52.3)	31	(47.7)
Married/cohabitated, *n (%)*	71	(60.2)	38	(66.7)	33	(54.1)
Gross family income, *n (%)*						
≤ 400,000 NOK, *n (%)*	46	(39.3)	35	(41.0)	23	(37.7)
> 400,000 NOK, *n (%)*	71	(60.7)	33	(58.8)	38	(62.2)
Education (1-3)						
Low: Upper-secondary school or below, *n (%)*	44	(37.6)	17	(29.8)	27	(45.0)
Middle: Upper-secondary school general studies, *n (%)*	21	(17.9)	15	(26.3)	6	(10.0)
High: University college and/or university, *n (%)*	52	(44.4)	25	(43.9)	27	(45.0)
Autonomous regulation (1-7), *mean (SD)*	6.1	(0.9)	6.1	(1.0)	6.1	(0.8)
Controlled regulation (1-7), *mean (SD)*	4.1	(1.2)	4.0	(1.3)	4.0	(1.1)
Amotivation (1-7), *mean (SD)*	2.3	(1.3)	2.4	(1.2)	2.3	(1.3)
Defiance (1-5), *mean (SD)*	1.9	(0.8)	2.0	(0.9)	1.9	(0.8)
Self-efficacy for PA (1-7), *mean (SD)*	4.6	(1.6)	4.4	(1.8)	4.7	(1.4)
Social support for PA (1-6), *mean (SD)*	3.2	(1.0)	3.3	(1.0)	3.1	(1.0)
Childhood experience of respect (1-7), *mean (SD)*	4.5	(1.8)	4.7	(1.9)	4.4	(1.7)
Low childhood experience of respect (≤ 3), *n (%)*	39	(33.1)	20	(35.1)	19	(31.2)
Self-esteem (1-7), *mean (SD)*	4.1	(1.7)	3.9	(1.7)	4.2	(1.6)
Low self-esteem (≤ 3), *n (%)*	46	(39.0)	27	(47.4)	19	(31.1)
Sedentary[a], in hours per day, *mean (SD)*	19.7	(2.1)	19.5	(1.9)	19.5	(1.8)
Moderate to vigorous PA[a], in hours per day, *mean (SD)*	0.9	(1.1)	0.9	(0.6)	1.1	(0.9)
≥ 150 minutes of MVPA per week, *n (%)*	92	(79.3)	43	(75.4)	49	(83.1)

Abbreviations: RCT: Randomized controlled trial; SD: Standard deviation; BMI: Body Mass Index; NOK: Norwegian Kroner; SD: Standard Deviation; PA: Physical activity, MET: metabolic equivalent. Time spent sedentary < 1.5 METs; Moderate to vigorous intensity physical activity (≥ 3 METs). a) Physical activity monitor worn ≥ 4 days.

4.4 Paper IV

The last paper presents the results of the HLCs' behaviour change interventions on time spent in MVPA and in sedentary behaviour six months after baseline. The RCT did not identify any effect of the interventions compared to the controls (Table 2). The participants' MVPA at baseline was the strongest predictor. Across both groups, 83% achieved 150 minutes of MVPA per week (no bouts). However, participants who were least active in the intervention group increased their MVPA significantly compared to the least active in the control group (from the interaction analysis: B = - 0.59; 95 % CI: - 0.65 to - 0.25; $p < 0.001$). The adherence rate was 70%. Older age predicted attendance, with no difference across gender. Participants with mental health challenges, musculoskeletal challenges, or chronic somatic disease were more likely to drop out. Participants with higher education levels were more likely to drop out compared to those with middle education.

Several characteristics of disadvantage at baseline (low self-efficacy and low social support for physical activity and type of motivation) did not explain changes in MVPA, but individuals with mental health or musculoskeletal challenges, or lower levels of education were less likely to improve their level of MVPA. The difference in MVPA widened between the education groups, regardless of whether they received the interventions or not, and the interventions did not seem to mitigate these differences. The results do not support placing a strong emphasis on individual behaviour change interventions as a health promotion strategy. A longitudinal cohort study 24 months after baseline will reveal the participants' ability to maintain a high level of MVPA, and predictors of MVPA in the long-term.

Several factors may explain why this study did not identify an intervention effect. Surprisingly, our participants were already physically active at baseline, thus making it hard to identify an additional intervention effect. A health behaviour survey, wearing an activity monitor and possibly receiving feedback on results may have increased MVPA in already motivated individuals.

Table 3 Results from multiple regression analyses of change in time spent MVPA and sedentary after six months for the participants in the RCT of the Norwegian Healthy Life Study recruited from June 2014 to September 2015.

	Baseline			Post intervention			Regression		
Outcome Group	**N = 115**	**Mean**	**SD**	**n = 81**	**Mean**	**SD**	**b[a)]**	**95%CI**	**p-values**
MVPA[b)]									0.735
Intervention	56	0.90	0.62	38	0.92	0.67	0.00	(reference)	
Control	59	1.11	0.87	43	1.14	0.70	-0.04	(-0.25, 0.18)	
Sedentary PA[b)]									0.276
Intervention	56	19.52	1.91	38	19.43	1.82	0.00	(reference)	
Control	59	19.47	1.83	43	19.48	1.27	0.23	(-0.18, 0.64)	

Abbreviations and symbols: PA: physical activity; RCT: randomized controlled trial; SD: standard deviation; b: standardized regression coefficient; CI: confidence interval; MVPA: Moderate to vigorous intensity PA: ≥ 3 METs; Sedentary PA: hours per day spent < 1.5 METs; METs: metabolic equivalents

a) Between group difference adjusted for baseline values; b) results based on physical activity monitor ≥ 4 day at baseline and ≥ 3 days at six months

5. Discussion - Methods

In this this chapter we discuss selected methodological issues and results. Due to essential methodological differences between the two studies, we have split the discussion of strengths and limitations into two sections, one for each study. The generalisability of the results is discussed in the next chapter.

5.1 Study 1 The systematic review

5.1.1 Validity challenges

As far as we know, this was the first meta-analysis with meta-regression using the BCTTv1 to identify effective BCTs for promoting physical activity and healthy eating for obese adults, and the first review of BCTs to explore the association at two time-points: short (≤ six months) and long-term (≥ 12 months). The review included participants similar to the HLC population, strengthening its relevance and external validity for this setting. Our study population had a mean BMI ≥ 30 kg/m^2, a mean age ≥ 40 years, and was in need of diet and/or physical activity interventions in order to improve health. In a similar review in 2012, Dombrowski and colleagues used a taxonomy of 26 BCTs, and explored the association between BCTs and weight reduction among obese adults. However the review's inclusion criteria required an additional risk of morbidity or co-morbidity (93). Like the HLC participants, the study participants did not need to have an NCD for the study to be included in the review. We acknowledge, however, that being obese and middle aged are associated with several obesity-related diseases.

Systematic reviews typically focus on synthesising only quantitative studies to evaluate *what works* without considering *how*, *for whom*, and *in what context*. In order to overcome this limitation, we adopted a realist lens and asked how the effect might vary across a range of intervention characteristics, different populations and places, in addition to different time frames.

We identified 6283 potentially relevant studies (database search 6203 studies, reviews 36 studies, scientific journals 44 studies) of which 48 met our inclusion criteria (Paper I, Figure 1 Flow Diagram,). We collected data on several study characteristics that might influence the interventions' effects (Paper 1, Additional File 2 and 3). Two researchers independently identified the risk of under or overestimating the intervention effect based on recommendations in the Cochrane Handbook of systematic reviews (140). We solved disagreements by discussion (Paper 1, Additional File 4). We did not exclude the few studies that lacked information on attrition, or those that did not adjust for loss of participants in analyses, but judged them as *unclear,* or of *high risk* for attrition bias. We judged studies that did not report, or lacked information on pre-specified primary outcomes, to have *high* or *unclea*r risk of reporting bias. Selective outcome reporting was associated with intervention effect in the short-term. Our funnel plot of short-term reports showed a symmetrical (inverted) funnel as a manifestation of absence of publication bias (Paper 1, Additional File 8). The funnel plot of long-term results documents an over-representation of small studies with low effects (Paper 1, Additional File 9). Publication bias was therefore unlikely also for long-term results.

Extraction of intervention effects estimates were collected at three time points if available: 1) at baseline; 2) short-term (≤ six months after baseline), and 3) long-term (≥12 months after baseline). For this review, we did not select the most favourable outcome results per study. Paper 1, Additional File 2 presents the range of outcomes reported per behavioural domain. The effect sizes between physical activity and diet studies were vastly overlapping. We joined both domains, because we wanted to study the effect on behaviour change *in general*, and not within the specific behavioural domain.

We identified six types of effect measures: 1) baseline and follow-up data per group; 2) data of change within each group; 3) follow-up status per group; 4) estimates of difference of change between groups; 5) numbers and fractions of participants who reached behaviour goals at follow-up, and 6) standardised effect sizes between groups

(e.g. Cohen's d). In some studies, it was impossible to adjust for baseline values. When a study reported outcome measures for change in both physical activity and diet, we treated them as separate results in the analyses. In order to avoid double counting of participants and underestimating the variance associated with each effect size, we halved the group size per behaviour domain. We cannot rule out that the methods for effect size estimation may explain some of the between-study variations, as we did not adjust for this in the meta-regressions.

Using taxonomies to identify effective BCTs in interventions has several limitations. The results from initial searches in databases were extensive. After checking for inter-rater correlations for inclusion, one researcher extracted studies based on the title. This may have resulted in fewer studies than the number we initially could have included from database searches. However, an additional check of reference lists of several relevant reviews and four scientific journals resulted in only a few new titles.

Two researchers checked all abstracts for inclusion. Consistent BCT coding across several coders is challenging due to differences in professional competence and values. We tried to counteract this and develop a united understanding of coding by two reviewers taking a web-based educational course in BCT coding. The third reviewer is a psychologist and experienced counsellor in alcohol and drug treatment. We coded several study interventions independently and discussed the results afterwards. Despite this, we cannot disregard the fact that differences in coding practice may have influenced the results.

Based on previous critiques of reviews, we identified the BCTs exclusively delivered to the intervention group, removing BCTs that were applied across both intervention and control groups. Information about the control group, such as usual care or waiting list, are often missing or lack detail. This might have affected the accuracy of the coding.

Even though it was possible to identify effective BCTs, one BCT seldom worked alone. A range of BCTs usually work together and in relation to social context and practice. In addition, a combination of BCTs is also dependent on mode (one-to one, group or web-based), duration of contact (time and frequency of contacts), and choice of methodological approaches, e.g. directive or autonomous supportive counselling. These factors have probably mediated and moderated the effect of the BCTs. We tried to account for such differences by including mode of delivery and counselling methods as characteristics of the studies.

Identification of the BCTs used in the studies was at times difficult due to the quality of reporting and limited information on the content of interventions. Only a few studies based the intervention on a manual or reported intervention fidelity. Many of the interventions emphasised a patient-centred approach and the importance of basing the counselling on participants' needs. However, we do not know to what extent the BCTs applied were identical with the interventions described in the paper. Many of the possible 93 BCTs were seldom or never identified but this does not mean that they were not used. It could mean that they were not reported in the articles, or that descriptions of intervention design did not provide enough details.

We pooled BCTs in interventions for two different behavioural domains in the tests. We cannot rule out the effectiveness of BCTs on specific behavioural domains or for specific population groups. In addition, it is important to note that a BCT should not be deemed ineffective based on one review. Rather, the taxonomies can be used to identify ineffective BCTs that lack supporting evidence from more than one study.

Additional File 1 in Paper 1 describes how we compared the results from several related studies in a systematic manner. Statistical approaches were used to re-express into odds ratios (from dichotomous data) as standardized mean difference allowing dichotomous and continuous data to be pooled together (Hedges' *g*). I^2, a measure of heterogeneity, and was 71% and 59% in the two outcome reports. However, recently statisticians have warned against the interpretation of I^2 as a heterogeneity index

(176). I^2 does not tell how much the effect size varies, but rather the extent of inconsistency of findings across the studies that are included. Instead, statisticians advocate reporting the range of effects, termed as the prediction interval.

We applied meta-regression and investigated if study characteristics (potential effect mediator) might account for the heterogeneity of the interventions' effect. Supplementing meta-analyses with meta-regression is a method for overcoming the threat heterogeneity represents for the validity of meta-analyses. Additional File 6 and 7 in Paper 1 presents the actual number of covariates assessed in meta-regression models. The potential of false-positive results with many analyses should also be recognised. We have reported the explained between-study variance as R^2 and found that 58.8% and 100% of the variance was explained by variables entered in the meta-regression analyses for short and long-term results, respectively.

Systematic reviews and meta-analyses have been criticised by researchers and clinicians who prefer the conventional review article (177). Several large RCTs have produced evidence that contradicts the results from meta-analyses of small trials. In other cases, systematic reviews that address the same issue have reached the opposite conclusions. The results of systematic reviews will always depend on the methodological quality of the included studies (garbage in - garbage out), and publication bias may provide serious problems for the analysis. The most favourable outcome results are generally reported, while results pointing the other way remain mostly unpublished, or are published at a later time (time lag bias) (177). In spite of this, systematic reviews based on a pre-published research protocol, a systematic search of studies, together with a critical review of their methodological quality, are considered by many to be more reliable than traditionally narrative reviews (177).

5.2 Study 2 The Norwegian Healthy Life study

This part of the thesis includes a paper presenting the study protocol (Paper II), a cross-sectional study exploring the HLC participants' characteristics and MVPA at

baseline (Paper III) and an RCT of the intervention results on MVPA six months after baseline, compared to a control group (Paper IV).

5.2.1 Design

We wanted to evaluate the effect of the interventions on MVPA with an RCT design. Experimental design offers the most rigorous control over extraneous variables and supports strong internal validity. However, RCTs have been criticised for focusing on effect size, ignoring process and for being inappropriate if the context of the interventions differs across local sites (178). The context includes anything external to the intervention that may act as a facilitator or as a barrier to its effect (78). To compensate for this critique, evaluation of complex interventions may integrate *realist principles* and update the understanding of the interventions' effectiveness with what works, for whom and under what circumstances (179). Using a *realist lens*, we acknowledge that the HLC interventions interacted with the behaviour, beliefs and experiences of multiple stakeholders and participants through time, space and resources (human and physical). The HLC model is tailored to local conditions and local ownership (priorities, resources and competence available in the municipalities). However, we maintain that the shared understanding of the key intervention functions of the HLC model, such as objectives, process, methods, and theoretical input may improve effectiveness over excessively standardised intervention content and delivery (178).

5.2.2 A pragmatic randomised controlled trial with a longitudinal follow-up

We wanted to evaluate a new health service which was already in routine practice in primary care. In real-world settings across eight municipalities the intervention mechanisms were already interacting with contextual characteristics. The research group addressed the complexities in contexts through focus groups with stakeholders across all eight municipalities in order to capture their perspectives on the barriers and facilitators of the HLCs, and insights into potential conflicts (9). In addition, we

collected information about the local adaptations of the programme, methods, competence, and resources available at each site. We maintain that our procedures strengthened the external validity of the study results.

From 2014 to the end of 2017, the research group and personnel at the HLCs met at a seminar every six months. The aim of the seminars was to develop a mutual learning network, and the seminar content is presented in more depth in Paper II. The learning network also provided HLC personnel with an opportunity to visit other HLCs and to give and receive peer support. For the research group the seminars provided an arena to present and exercise counselling approaches within the frame of client-centred methods, with a special emphasis on MI. We also presented preliminary scientific results and discussed possible interpretations and conclusions. The network distributed a regular newsletter to the HLCs with relevant information, such as newly published scientific papers. We believe this dialogue and co-learning supported the quality of the interventions by recognising the importance of harnessing evidence within the local context. It is therefore unlikely that an HLC outside this network could provide better intervention results than these centres did.

In the RCT, the HLC model was standardised by purpose (aims, functions, methods), and not by the actual active intervention ingredients. This allowed the local mechanisms to take different forms while achieving the same objective. We believed that interventions tailored to local conditions would provide more convincing evidence of effect (178). The Directorate of Health had not developed a logic model (programme theories) describing the causal assumptions underpinning the HLC interventions. As researchers, we therefore adopted a simple and pragmatic approach by asking if this model as a whole was effective or not (180).

Random assignment, as used in the present study, eliminates the following threats to internal validity: selection, history, maturation, regression, testing, and instrumentation. Experimental mortality (attrition) during the study period may create bias and differences in post-test outcomes. However, we experienced equivalent loss

of participants across groups (181). We did not receive permission from the Regional Committee of Ethics to ask participants why they dropped out. Therefore, we could not account for their reasons or detect any possible variation between groups. Information about how the participants were referred to the HLCs could have provided important additional information, e.g. regarding the impact of being self-referred compared to being referred by others. Unfortunately, this information was not available. There is no standard system across the HLCs to identify referrals (who referred), uptake (who started), or completers (who finished). Another threat to the internal validity was an attrition rate of over 20%, affecting the statistical power of the study to detect a change in behaviour (Type 2 error). This is discussed in more depth in Paper IV.

We safeguarded the random allocation of participants to intervention and control conditions. Allocation concealment prevented study personnel from foreseeing the next assignment. Blinding of participants and HLC personnel was not possible and the outcome measurements may be influenced by this. The Hawthorne effect is the effect created by the person's knowledge that they are receiving an intervention or not. However, this objection is more relevant when the study reveals effects in favour of the intervention.

The behaviour change interventions are described in Paper II. There is no intervention manual for behaviour change counselling to support local intervention design and implementation. Therefore, it is difficult to distinguish between an adaptation that makes the intervention fit better within a local context, or changes that might undermine intervention fidelity (78). To conclude with no intervention effect if the interventions were not properly implemented would represent a Type 3 error (dismissal of the intervention effect, because the intended behaviour change components were not fully implemented) (113).

We selected MVPA as the primary outcome because exercise is the main activity at the HLCs and this is where the majority of personnel have their competence. We

chose to evaluate the results after six months to allow the interventions to initiate a change in behaviour, and for the new behaviour to be adopted in daily life. Six months was confirmed to be the mean duration for participants' attendance. Validation and tests of SWA indicated that the armband was appropriate for the aim of the study, measuring physical activity in inactive, free-living, overweight or obese individuals. We wanted to minimise the workload for personnel administering the monitors, and we had prior experience that SWA was easy to administer. We lost SWA data from five participants due to technical problems with the monitors, resulting in 81 who completed all parts of the study (monitor plus survey), compared to 86 people who answered the survey (Paper 1, Figure 1).

According to a recent Norwegian population study, men and women of normal weight (≤ 24.5 kg/m^2) were physically active at a level of moderate to vigorous intensity 42.5 minutes per day (in bouts ≥ 10 minutes, measured with ActiGraph) (20). This represents 5.5 minutes more than overweight individuals (25-29.9 kg/m^2), and 14.3 minutes more than obese men and women (≥ 30 kg/m^2) (20). Based on a former study, we estimated that an increase in MVPA of 10 minutes per day in the intervention group would represent a realistic and clinically relevant change in behaviour (175). Our population had a mean BMI of 34.0 kg/m^2. In line with this, a baseline mean MVPA approximating 20 minutes per day (SD 15) was a realistic estimate.

National recommendations for MVPA claim that it should have at least 10 minutes' duration in order to have health benefits. The evidence for this criterion is limited, and may not be included in future recommendations (26). In line with this, we reported total physical activity regardless of duration. We did so believing that any increase in MVPA, including MVPA with no bouts, is beneficial for inactive people and an important step forward in becoming more active (25). Our method overestimated time spent in MVPA compared with other studies reporting minutes of MVPA in bouts. Reporting MVPA in bouts of 10 minutes in addition to total MVPA would have made it possible to compare our results with other studies. We recorded

sedentary time per day including time spent sleeping. A Norwegian population study defined wearing time with the accelerometer as 24 hours, subtracting 6 hours for sleeping and 3.3 hours for non-wearing time (175). When we applied the wearing time calculation for obese people and adjusted for gender in our study, we estimated 69% sedentary time, compared with 63% in the population study.

We randomised participants after the collection of baseline data. We did not test for baseline imbalance between intervention groups. After proper randomisation procedures 5% of the variables may differ significantly (182). Paper III, Table 1 presents the description of the intervention and control groups.

We included all randomised participants in the analysis by the intention-to-treat principle, in accordance with CONSORT guidelines (183). We evaluated if dropout could explain the intervention effects by baseline-observation-carried-forward (BOCF). We assumed BOCF to be a conservative estimate for imputation of missing values at post-intervention. BOCF assumes that the dropouts did not increase their MVPA, and the baseline values replace the missing post-intervention values. We performed complete case analyses and analyses based on BOCF and the conclusions were identical. The results of these procedures should have been reported in paper IV.

Since the analyses revealed no intervention effect and the attrition was equal in numbers between groups, we considered the risk of bias in effect estimates as improbable. We therefore used analyses of covariance (ANCOVA) and adjusted for the baseline values. This is considered by many as the best method when comparing two treatments in an RCT where the outcome variable is measured before and after treatment (182).

The reliability of measurement instruments was safeguarded by using validated scales and an objective, validated measure for levels of physical activity. The targeted constructs were based on theoretical and empirical evidence that explain and predict behaviour change (convergent validity).

A research study protocol and training of the HLCs' personnel supported the similarity of the experimental conditions and data collection. Using an online survey and sitting in a secluded area permitted the participants to answer the questions in accordance with their honest opinions. We measured the level of physical activity over a period of several days.

Restriction of range within variables may reduce the power of the experiment and increase the chance of Type 2 error. As mentioned in Paper IV, autonomous regulation and amotivation were affected by a ceiling and floor effect, and this may have reduced their ability to predict behaviour change (181). A similar ceiling effect appeared in a study comparable to ours, although autonomous motivation predicted long term maintenance of PA (184). The wording in the TSRQ presents several reasons to change health behaviour in general. It is possible that a change in wording more in line with increasing physical activity would have differentiated more between groups.

In addition, choosing a significance level of 0.05 implies that 5% of the cause effect covariation (association) will occur by chance alone and this needs to be taken into consideration. Analysing the data for relationships and hypothesis testing always involves a set of risks for Type 1 error. This study performs multiple analyses of predictors and moderators and this may have inflated the risk of finding one by chance alone.

We were surprised to find that the participants had high levels of MVPA at baseline. We addressed the issue at the seminars with the HLC personnel who attributed these results to the use of SWA. There is evidence that using an accelerometer, either alone or in combination with other intervention components, improves physical activity (185, 186). To check if the data was a true measure of physical activity behaviour we used a correlation test of the two survey questions on physical activity "How long are you physically active each day?" and "How hard do you exercise?". The answers to self-reported exercise questions were significantly correlated with MVPA measured

with SWA (Pearson Correlations $r = 0.28$, $p < 0.002$ and $r = 0.41$, $p < 0.001$ respectively). When we used the questions as post-outcomes (ANCOVA with adjustments for baseline values), the analyses still revealed no difference in effect across groups.

The SWA measures bodily movement but adds different measurements in the algorithms. It is difficult to identify one physical activity monitor as being superior. Technical characteristics of an instrument vary between the monitors and influence measurements, e.g. time spent at different intensity levels and total EE (39, 42). We chose SWA to measure levels of physical activity in overweight and obese adults in low intensity daily life activities. The SWA has been recognised to underestimate total EE and to overestimate time in MVPA (42). However, by using the same monitor on each occasion we maintain that the SWA was a reliable instrument to capture changes in behaviour across a group of inactive, overweight or obese adults (43).

In order to achieve statistically significant improvement, the intervention group needed to attain a very high absolute change in time spent in MVPA. Evidence of no effect between the intervention and the control group in this RCT may have several explanations: 1) there was no difference in results between the groups; 2) a ceiling effect caused by selection of the most active participants, or a motivational effect from wearing the monitor; 3) the intervention effect on MVPA between groups was less than our power analysis presupposed (10 minutes per day), or 4) the population still participating at six months was too small to detect a between-group difference in behaviour with an 80% statistical power and a 5% significance level (low statistical power).

5.2.3 Statistical analysis

In order to answer what works, for whom and under what circumstances, we explored how intervention effects varied according to the characteristics of participants or

subgroups, and we examined the potential effects of mediators and moderators on the results.

Prior to the analyses, we split the TSRQ into the composite scores autonomous and controlled regulation for behaviour change and amotivation. The internal consistency of the different composite scores was satisfactory and is described in Paper III. Before analyses, we randomly reviewed 10% of the questionnaires and checked the direction of the scaling of answers.

In the linear regression analyses Table 4 (Paper IV), we performed *pairwise exclusion* of missing data in order to preserve statistical power. This means that the case (person) was excluded only if they had missing data required for the specific analysis. They were included in the analyses for which they had necessary information. The alternative *exclude cases listwise* would have limited the sample size and affected statistical power.

5.2.4 Ethics and approvals

Participants signed an informed consent prior to participation in the study. The Regional Committee for Medical and Health Research Ethics approved the study. Ideally, we should have designed an RCT with a true (external) control group who received routine care and compared these with an HLC intervention group. However, the complexity of such research design and resources (time and cost) was beyond the scope of this evaluation. Besides, such a design would have missed the self-referrals. We discussed the ethics of making the control group wait 6 months before receiving the intervention. The arguments against claimed that the control group would lose the motivation to change their behaviour. In reality, 91% of the control group achieved the national recommendation of MVPA six months after baseline.

We are well aware that an RCT gives priority to the internal validity of an intervention study, sacrificing some of its external validity. Therefore, we have been cautious interpreting the results of the study. In the future, we will also study other

outcomes such as quality of life, dietary changes, eating and body cognitions, sleep quality, and weight change. We will also evaluate long-term results (24 months) in order to make more confident conclusions concerning the effect of HLC interventions.

6. Discussion - Results

6.1 Study 1

This systematic review provides evidence of effective BCTs in counselling for behaviour change. The interventions for participants similar to those attending the HLCs were moderately effective in the short-term, and with somewhat reduced effect in the long-term (with overlapping CIs). The reduction over time may be explained by the fact that reasons and barriers for change are personal and embedded in the individual's social practice (67). Even if the behaviour was changed initially, social and environmental factors tend to shape the return of previous behaviour (187). The BCTs *goal setting* and *self-monitoring of behaviour* were associated with the intervention effect in both the short and long-term. Using several BCTs, and especially *goalsetting of outcome*, *setting graded tasks*, *receiving feedback on outcomes of behaviour*, and *adding objects to the environment*, such as a step counter, supported long-term change.

Previous reviews have either used the 26 or the 44 BCT taxonomy or targeted other populations or different behaviours, limiting our ability to compare results. In line with our results, a review of interventions targeting low-income groups recognised that the BCTs *goalsetting* and *setting short-term goals* were associated with intervention effects. In addition, this review demonstrated that social support could explain change in health behaviour (188). As far as we know, no previous reviews have associated the BCTs a*dding objects to the environment,* e.g. a step counter, with effect on health behaviour. However, several other studies support the use of the BCTs *goalsetting of behaviour*, and *self-monitoring of behaviour* (92, 93, 98). Unlike previous reviews on effective techniques, we identified that a person-centred and autonomy supportive counselling approach added to the effect in the long-term (93, 98). According to SDT, being autonomous is important in maintaining behaviour change (119-121). All BCTs aim to support the individual's self-regulation of

behaviour and, according to theorists, we have limited psychological energy for self-regulation (84). However, when our actions are self-determined our resources are renewed. We are able to maintain change for a longer time and may develop new habits.

Our results support other researchers in the claim that once the individual is ready for change it is more effective to promote self-regulation skills and autonomous motivation (93, 189). The combination of BCTs that support the development of self-regulation skills (*the how*) and an autonomy supportive and person-centred approach *(the why)* seem important in order to maintain change. Regulatory techniques and communication style are not antagonists, but should exist together in a productive balance in counselling (168).

Several reviews provide evidence that using a number of different BCTs is associated with increased effectiveness, and our results support this claim (96, 97). We found no evidence that the study characteristics, such as trial setting, source of delivery, being individual or group-based, intervention duration, targeting one or two behavioural domains, or collecting objective versus self-reported data could explain differences in the study effects. There was no evidence that interventions based on theories of behaviour were superior to those that were not. However, we did not explore if and how the theories were applied in the intervention design. Despite this result, it is increasingly recognised that building intervention designs on theoretical frameworks is likely to be effective in targeting causal determinants of behaviour, and can facilitate an explanation of why the interventions work (72). Interventions that target these determinants may give a larger effect size, or the same effect at lower costs (190).

Local stakeholders want their HLC interventions to be based on evidence of effect (9). The Directorate of Health's recommendations for the HLC interventions are not specific on how the counsellors should move from *why* the participants should change their behaviour to *how* to regulate their behaviour. The results of Paper 1 may help

counsellors to develop effective intervention means at the HLCs and to identify competence needed in counselling.

6.2 Study 2

Results from Study 2 revealed that the HLCs' participants were predominantly middle-aged, obese, physically active females motivated for change. Paper III gave evidence that the HLCs recruited participants with low education and family income, in line with the Directorate's intention to mitigate health inequity. However, 44% of the participants also presented with University College and University education, compared to 34% in the Norwegian population as a whole (191), and 52% in a Norwegian population survey (20). Two out of five reported low self-esteem and one in three had experienced low respect and appreciation in childhood. These characteristics of disadvantage were associated with several important predictors for maintenance of change: controlled motivation for change; low self-efficacy, and social support for PA (85). We found no association between level of physical activity and education, type of motivation, or self-efficacy, but having low self-esteem and psychological problems were associated with being more sedentary at baseline.

Paper IV presented evidence of no effect of the interventions on time spent in MVPA or sedentary six months after baseline. The strongest predictor was the participants' MVPA at baseline. It is difficult to compare intervention effects on physical activity across research studies because each study has considerable variation in intervention and control conditions concerning if, how and when change in behaviour was reported. In Paper IV, we compared our results with RCTs of the ERS interventions included in two reviews (58, 59, 67). Only three RCTs reported the effects on PA at a moderate level of intensity compared to routine care. The results were no or small effects on increase of physical activity at 6 - 12 months, compared to advice, written material or information on locally available physical activity facilities (63, 192, 193).

In sum, these results and the result of the present study do not produce evidence of beneficial effects from physical activity interventions in community or primary health care, at least not over time.

Interventions like those delivered at HLCs may not be effective for participants in general, but our RCT confirms that they may be effective for participants who were physically inactive at the start. However, the results indicate that differences in physical activity between educational groups widened during follow-up. This effect was independent of whether they received the intervention or not, meaning the intervention did not mitigate these differences. Individual interventions to target health behaviour have the potential to increase health inequalities. Reducing health inequalities depends on interventions that are differentially effective favouring those with a disadvantaged background (188). To our knowledge, no studies of HLCs or ERSs have compared the intervention results against level of education or income. One ERS study that included residents from disadvantaged neighbourhoods, among other groups, reported that even though the ERS service reached the more deprived areas, this group was less likely to start (uptake) and to complete the interventions (194).

A study from Great Britain compared the ERS to other types of physical activity promotion in primary care and found them equally effective compared to other potentially lower cost approaches (195). The results led the National Institute for Health and Care Excellence (NICE) to change the recommendation from ERS to brief advice about physical activity in daily life (in cases where the aim was to increase physical activity level only) (71). Bearing in mind that the HLC participants represent a wide variety of health problems, we cannot disregard the fact that the interventions may be more effective on certain subgroups (196). A Welsh RCT of ERS over 12 months identified significant improvement in both physical and mental health and in physical activity for participants with risk of CHD (63). Even though people with mental health issues did not increase their physical activity, their anxiety and depression levels were significantly reduced.

The positive results for participants referred with CHD or mental health challenges in the Welsh RCT were highly dependent on adherence to the program (63, 66). Paper IV presented evidence that having a mental, musculoskeletal or chronic somatic disease increased the risk of dropping out of the interventions. This could indicate that these vulnerable groups had a lower chance of success because their starting level undermined attempts to be physically active. If the HLCs intend to impact social inequalities in health, the interventions need to favour those belonging to the most vulnerable groups and to support them in adhering to the program, e.g. those with clinical disease or with low education (188).

Nearly 80% of the participants reached 150 minutes of MVPA per week at baseline, compared to 31% in a Norwegian cross-sectional study (175). The Norwegian public health studies report time spent in MVPA in bouts above 10 minutes' duration. We reported all MVPA regardless of duration in Papers III and IV in order to identify several smaller changes in the participants' lives, such as taking the stairs rather than using the elevator and breaking up longer periods of inactivity.

6.2.1 Strengths of the study

We conducted a pragmatic RCT in a real-life setting. We have presented results that are most relevant for overweight, motivated, physically active participants at the HLCs. The generalisation of our results may therefore be limited to this population. The participants came from HLCs in small rural or bigger urban areas across eight municipalities in Norway and represent the variation in HLCs across the country. We evaluated if national recommendations for the HLC model and shared understanding of key intervention functions at six HLCs as a whole produced an intervention effect. We therefore conclude that this RCT, which is the first trial in the HLC domain with a long-term follow-up, generates important evidence related to the HLCs' ability to improve health behaviour and prevent NCDs as part of a public health promotion strategy.

6.2.2 Limitations

In Paper IV, we discuss factors that may explain why we did not find any intervention effect. Only 34% of the participants eligible to take part in our study agreed to be randomised, thus increasing the chance of selection bias. However, uptake of participants was in line with results reported in two reviews, from 35% to 100% (59), and 14% to 62% (14). In a recent HLC study, only 14% of those identified with a high risk of type 2 diabetes in a public health survey accepted the invitation to participate in the study (197). There is evidence that participants who volunteer to take part in an exercise study have better health and higher levels of physical activity than those who decline (198). In our study, it is possible that those who declined to participate were less physically active than those we recruited. However, our study also included less active individuals.

Many HLC participants had high levels of physical activity before entering the interventions. The participants may have been inspired to a high level of MVPA by questions about health behaviours and motivation, wearing an SWA for a week and possibly receiving personalised information about their results. Evidence from our systematic review (Study 1, Paper I) demonstrated that *goalsetting* (e.g. talking about the importance of 150 minutes of physical activity per week), and providing an SWA to *monitor behaviour*, are BCTs associated with intervention effect. *Receiving feedback* on progress from a counsellor, e.g. SWA results, was also identified as a BCT (91). There is evidence that those motivated for change may benefit from brief advice (71, 199), the use of an activity monitor (185, 200), and being asked about health behaviours (201). Our results indicate that among the HLC attendees who agreed to participate in the study, there is a group who are highly motivated and have already attained high levels of MVPA. These participants may probably achieve the same results with a less intensive intervention. The Swedish recommendation for behaviour change differentiates levels of intervention between participants: brief

advice 5-10 minutes; more detailed advice 10-15 minutes dialogue, and high intensity counselling over a longer time period (70).

We also hypothesised that individuals lacking motivation, capability, or opportunities for change were less likely to attend or be enrolled in the interventions. After all, people are more likely to take part when motivation is high and barriers for change are low (84). According to the HLCs' stakeholders, self-referred participants were more motivated and less likely to drop out (9). In a qualitative study of obese HLC participants, nearly 50% of the attendees came on their own initiative and not due to referrals from professionals. They knew what to do, but needed HLC support to get started (54). We had no data on the number of self-referrals in the present study, but we knew that only 19 out of 118 felt pressure to attend. Taken together we may maintain that selection and monitoring caused a ceiling effect concerning physical activity and motivation.

Across intervention studies, the initial uptake of study participants is often not mentioned, or is measured differently, e.g. uptake may be defined as initial attendance or enrolment following referral (59). Attendance may also be defined differently across studies, e.g. completion of a number of sessions, a percentage of attendance, or completing the exit consultation. In 2015, Campell et al reported attendance to be 37% across trials of ERSs (59). There was no standard definition of the participants' attendance across the HLCs. In our study, many participants reported impaired health, and this also predicted increased dropout rates. We also revealed that 73% of participants completed the survey after six months. However, this rate is lower than we anticipated affecting the statistical power of the study. It is also possible that the intervention effect on MVPA between groups was less than our power analysis presupposed (10 minutes per day).

7. Conclusions and implications

As part of a public health promotion strategy, the Norwegian NCD strategy placed a strong emphasis on individual interventions for behaviour change. The results from Study 2 do not provide evidence that the HLCs impacted MVPA during six months' follow-up. However, the high level of MVPA at baseline in both groups indicated that the external validity of the study may be limited. We confirmed that those least active at baseline benefitted most. It is unlikely that interventions encompassing already physically active people will improve population health or mitigate social differences in health behaviour. Those already motivated for change in physical activity may benefit from less intensive interventions, such as brief advice and the use of a physical activity monitor.

The most effective strategy to promote health and prevent NCDs is built on an ecological understanding of health, combined with individual approaches for vulnerable groups. It is essential to develop methods and techniques in counselling that work for those most in need, and least likely to benefit from traditional intervention: those in poor health and with complex barriers to engagement. In the process of behaviour change, the HLC counsellors should use multiple, proven techniques in order to promote self-regulatory skill, such as *goal setting of behaviour* and *goalsetting of outcome*, *self-monitoring of behaviour*, *setting graded tasks*, and *adding objects* that support the behaviour change, such as a physical activity monitor. These techniques should however, always be presented in an atmosphere of autonomy support, personal respect and empathy.

7.1 Future research

Based on our findings, future research could:

- Evaluate the HLCs' intervention results on MVPA and sedentary behaviour after long-term follow-up.

- Evaluate the HLCs' intervention results after six months on healthy eating, self-reported health and wellbeing, tobacco use, sleep, and body attitude compared to a control group, and with a long-term follow-up.
- Explore how characteristics of the HLC participants mediate and moderate The short and long-term effect of different outcomes.
- Explore reasons for dropout in order to understand the mechanism of change and attendance (qualitative studies).
- Explore how the HLC counsellors use MI and BCTs (process evaluations) to inform the interpretation of interventions' process and evaluation data.
- Today the HLCs have different systems for registration of sociodemographic data, data on referral, uptake after referral, adherence, and dropout. Standardised routines for data collection are needed in order to enable studies to explore variation across the HLCs.

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9. Appendix

Paper I

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REVIEW

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Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses

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Abstract

Purpose: This systematic review aims to explain the heterogeneity in results of interventions to promote physical activity and healthy eating for overweight and obese adults, by exploring the differential effects of behaviour change techniques (BCTs) and other intervention characteristics.

Methods: The inclusion criteria specified RCTs with ≥ 12 weeks' duration, from January 2007 to October 2014, for adults (mean age ≥ 40 years, mean BMI ≥ 30). Primary outcomes were measures of healthy diet or physical activity. Two reviewers rated study quality, coded the BCTs, and collected outcome results at short (≤6 months) and long term (≥12 months). Meta-analyses and meta-regressions were used to estimate effect sizes (ES), heterogeneity indices (I^2) and regression coefficients.

Results: We included 48 studies containing a total of 82 outcome reports. The 32 long term reports had an overall ES = 0.24 with 95% confidence interval (CI): 0.15 to 0.33 and I^2 = 59.4%. The 50 short term reports had an ES = 0.37 with 95% CI: 0.26 to 0.48, and I^2 = 71.3%. The number of BCTs unique to the intervention group, and the BCTs goal setting and self-monitoring of behaviour predicted the effect at short and long term. The total number of BCTs in both intervention arms and using the BCTs goal setting of outcome, feedback on outcome of behaviour, implementing graded tasks, and adding objects to the environment, e.g. using a step counter, significantly predicted the effect at long term. Setting a goal for change; and the presence of reporting bias independently explained 58.8% of inter-study variation at short term. Autonomy supportive and person-centred methods as in Motivational Interviewing, the BCTs goal setting of behaviour, and receiving feedback on the outcome of behaviour, explained all of the between study variations in effects at long term.

Conclusion: There are similarities, but also differences in effective BCTs promoting change in healthy eating and physical activity and BCTs supporting maintenance of change. The results support the use of goal setting and self-monitoring of behaviour when counselling overweight and obese adults. Several other BCTs as well as the use of a person-centred and autonomy supportive counselling approach seem important in order to maintain behaviour over time.

Trial Registration: PROSPERO CRD42015020624

Keywords: Systematic review, Behaviour change techniques, Healthy eating, Physical activity, Meta-regression, Heterogeneity, Self-regulation

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Background

Health behaviour, such as physical inactivity, unhealthy eating, smoking and excessive alcohol consumption, are leading contributors to morbidity and premature mortality in Europe, due to the development of non-communicable diseases (NCDs). The World Health Organization (WHO)'s Global Action Plan urges national governments to develop NCD targets and public health strategies to improve people's health [1]. Obesity is associated with several risk factors, and many studies target weight loss as a primary outcome although it is difficult to maintain weight loss over time. Moreover, weight neutral interventions that encourage body acceptance, combined with healthy behaviour and wellbeing, can improve health without targeting weight loss [2].

There is a growing interest in the use of theories of behaviour change and a total of 83 theories are identified [3]. Theories like social cognitive theory, theory of planned behaviour, and the transtheoretical model explain why people adopt a behaviour, but provides little explanation of how the initiation and maintenance of behaviour might differ. A person's self-regulatory strength is a limited, but renewable cognitive resource. Over time, people who are motivated by their own needs and desires, find it easier to sustain the new behaviour [4]. Thus, the determinants of behaviour may differ across the different phases of the behaviour change process. Consequently, intervention techniques that help people initiate change may not necessarily have the same effect on behaviour maintenance. In accordance with this, a review summarizing 100 theories that explain maintenance of behaviour change, have identified five overarching theoretical themes, among them positive maintenance motives, and active self-regulation [5].

Behaviour change interventions use different strategies and behaviour change techniques (BCTs) to support a participant's self-regulation skills and resources in the change process. A BCT is defined as the smallest "active ingredient" of an intervention [6]. Recent developments within science of behaviour change has led to the definition of the first 26 BCTs, later 44 BCTs, and recently 93 internationally agreed and validated BCTs (the Behaviour Change Technique Taxonomy version1, BCTTv1) [6–8]. Several reviews have tested the associations between BCTs and the intervention effect. Michie and colleagues' study revealed no significant associations between BCTs and study effects concerning physical activity (PA) and improved diet [9]. The BCT self-monitoring of behaviour explained the greatest between-study heterogeneity. Nor did Dombrowski and colleagues, find significant associations between BCTs and PA outcomes [10], but the BCT providing instruction on how to perform the behaviour was associated with improved diet outcomes. McDermott and colleagues found no positive association whatsoever, but the BCT providing feedback had a significant negative effect [11]. Williams and colleagues reported that the BCTs action planning, providing instructions, and reinforcing efforts towards behaviour were associated with higher levels of PA [12]. Lastly, Lara and colleagues found the BCTs barrier identification and problem solving, planning of social support, and setting goals for outcome results, providing feedback, and the use of prompts, e.g. put a sticker on the refrigerator, supported better diet outcome results [13].

The evidence that theory based interventions leads to better outcomes is inconsistent [14–16]. However, using a number of BCTs congruent with Control Theory, have been associated with increased intervention effects, e.g. through combining self-monitoring of behaviour with goal setting, providing feedback on performance, and review of behaviour goals [9, 10].

Behaviour change interventions may also have different therapeutic approaches, e.g. Cognitive behaviour therapy (CBT), or Acceptance and commitment therapy (ACT) or be delivered by professionals using a certain communication style. Motivational interviewing (MI) is a client-centred method for enhancing intrinsic and autonomous motivation to change, and is often used synonymously with person-centered counselling. The taxonomies define the counselling methods as a separate BCT. In some studies MI based counselling has not been associated with intervention effects [10, 13], and Dombrowski and colleagues concluded that volitional planning and action strategies are more effective than MI [10]. Therefore, successful behaviour change may dependent more on volitional and positive motivation and self-regulation skills.

Self-determination theory (SDT) is one of the many theories that explain maintenance of change [5]. SDT claims that successful increases in physical activity or healthy eating are not maintained over time if the reasons for doing so are mostly controlling, e.g. external pressure. Evidence based on SDT suggests that health personnel may enhance their efficacy by positively influencing clients' motivation and thus, make the behaviour become more autonomously regulated and valued [17–19]. Conceptual overlap and similarities exist between the techniques in MI and interventions based on SDT. SDT based interventions often use MI techniques in counselling and SDT can help explain why MI works [20, 21].

Building on these theoretical assumptions, there is a need to provide further insight on the utility of BCTs in facilitating long term behaviour change. Is there a difference in effective BCTs associated with the initiation and maintenance of change? We hypothesized that autonomy supportive counselling emphasizing both self-regulatory BCTs and internal motivation give persistence of change over time. To our knowledge, this is the first

systematic review with meta-regression analyses using BCTTv1 to identify effective BCTs for PA and healthy eating among overweight and obese adults, differentiating short and long term follow-up. Our objectives were accordingly to:

1) Synthesize the evidence of behavioural interventions, aiming to improve PA and healthy eating among overweight and obese adults in short and long term, and
2) Examine to what extent intervention effectiveness varies across studies depending on BCTs and other study characteristics.

Methods

The reporting of this systematic review were performed in accordance with the Preferred Reporting Items for Systematic Review and meta-analysis guidelines (PRISMA) and Template for intervention description and replication (TIDieR) checklist and guide [22, 23].

Eligibility criteria

Eligible study designs included published, peer-reviewed, randomized and cluster randomized controlled trials (RCTs) of behaviour change interventions providing baseline and/or follow-up data at minimum 12 weeks after randomization. The intervention duration was set at ≥ 12 weeks to allow time for counselling to effect the behaviour change process. The interventions had to promote change in diet and/or PA, compared to usual care, waiting list control or less intensive interventions. Only interventions applying behaviour- and/or cognitive behavioural strategies were included, whereas we excluded simply educational studies, e.g. "giving information". A mean/median age ≥ 40 years and a BMI ≥ 30 kg/m^2 were required to recruit participants at risk of developing non-communicable diseases. For pragmatic reasons only papers in Scandinavian or English languages were included. In fact, only English-language articles were identified. There was no restrictions on the types of intervention setting. Main outcomes were objective or subjective behavioural measures of PA and/or diet at baseline, at short term follow-up (≤6 months) and at long term follow-up (≥12 months) when available.

Search method

The electronic databases MEDLINE, PsycInfo and EMBASE were searched in cooperation with the library service at the Medicine and Dentistry Library, University of Bergen, Norway. Articles published in peer-reviewed journals from January 2007 to April 2013 using a search strategy based on previous systematic reviews [10] with these adjustments were targeted; "Motiv* interview*" was added to the concept "psychological interventions", the search term "healthy eating" was added to "diet", and "physical activity" or "walking" were added to the term "exercise". Detailed search strategies can be obtained from the author. The initial search was updated once to October 2014. The reference list of relevant reviews on the topic of interest was also screened [19, 24–33]. Additionally, we manually searched the following journals: International Journal of Obesity; International Journal of Behavioural Nutrition and Physical Activity; Obesity Research and Clinical Practice; and International Journal of Behavioural Medicine. We enlisted all references in EndNote X7. The review was preregistered at PROSPERO with protocol and search strategy (CRD 42015020624).

Data extraction

After removing duplicate publications, we carried out a relevance check of 6283 articles. The first 100 titles were screened in cooperation using a data collection form, and discussed by two reviewers (GBS and EM). In the next step, 100 titles were screened independently two separate times. This procedure yielded 94 and 90% agreement between the reviewers. Disagreements were solved through discussion. Thereafter, identifications of titles were performed by one researcher (GBS). The screening yielded 584 relevant titles of which abstracts were obtained. The first 20 abstracts were screened independently by two reviewers (GBS and EM). Thereafter GBS and EM independently screened all obtained abstracts. There was a 85% agreement whether to 1) include, 2) exclude or 3) carry out a full text evaluation. If the study was an analysis of mediators or a subgroup analysis, we included the main intervention study. We obtained published protocols and published online supplementary materials if available. We also used this approach in data extraction.

Study and intervention characteristics were collected by GBS using two data collection forms and later checked by EM. The data extracted were in accordance with the eight first items of TIDierR checklist for describing an intervention; brief name of the intervention, intervention theory, description of the intervention, procedures (methods), who provided, how, where, when and how much [23]. We were unable to identify the outcome results in nine studies. The authors of six of these papers answered our request for more data; four of them returned the information and two were unable to produce the data. The latter studies were subsequently excluded. If the study targeted both PA and diet, the outcome results were extracted for each behaviour separately.

Coding behaviour change techniques

When the interventions mentioned "education", we coded BCT 4.1 instruction on performing the behaviour and 5.1 information on health consequences. When "training" was

mentioned, it was coded as BCT 4.1. This approach is previously used by Presseau et al. to acknowledge a minimum of educational strategies in the interventions [34]. A BCT was only coded when there was clear evidence of inclusion, e.g. the BCT had to be directly applied to the target behaviour(s): PA or diet. The 93 BCTs had to be rated as either present (1) or absent (0). Only BCTs identified by both researchers were coded as present. The BCTs in the intervention- and control groups were identified separately, and the BCTs exclusively applied in the intervention group were extracted. Only BCTs present in the intervention and absent in the control condition were thus recorded. This approach was used to explain the difference in effect as emphasized by Peters and colleagues [35], and used by MacDonald and colleagues [36]. In addition, we recorded the total number of BCTs of both intervention arms.

Coding of other study characteristics

The following characteristics that might influence the intervention effect were extracted: the number of different BCTs in the intervention groups as compared with the control groups; total sum of BCTs in intervention plus control group; duration of intervention in weeks; treatment setting; format of delivery (coded as individual versus group or mixed); source of delivery (coded as community or workplace versus primary care or hospital); theory-based interventions (theory mentioned or not); method-based interventions (coded as MI or SDT versus ACT, CBT, Health-at-every-size (HAES) or Mindfulness based interventions or other method, versus no method mentioned/unclear); and type of outcome data (objective versus self-reported).

Risk of bias in individual studies

GBS and EM independently assessed risk of under- or overestimating the intervention effects using a standard risk of bias form covering: random sequence generation; allocation concealment; performance bias; blinding of assessment; attrition; and reporting bias [37]. We made judgements according to three categories; "low risk", "high risk" or "unclear risk", and disagreements were resolved through discussions.. We evaluated the risk of bias due to the lack of blinding of outcome assessment as «low» when outcomes were objective measures, as for instance in the use of an accelerometer. All diet measurements were self-reported with a high risk of performance bias (except vitamin C in blood in one study).

Extraction of effects

Where studies employed more than one intervention arm, the most active intervention and the most passive comparison were selected. We collected outcomes at the following time-points if available: 1) at baseline; 2) post intervention (≤ six months after baseline) in order to identify initial change in behaviour; and 3) at last follow up (≥12 months after baseline) in order to identify maintenance of change. (See arguments for these two time points below.) Where the studies reported more than one outcome per behavioural domain, we sought and extracted outcomes in the following order of priority: 1) measures defined as the primary outcomes; 2) objective measurements; or 3) the most comprehensive measurement (e.g. total fat consumption was preferred over saturated fat). All cluster randomized studies were checked whether they accounted for clustering in their analysis. Effect estimates based upon adjustments for loss to follow-up were preferred above effect estimates of completers only. Conservative estimates were preferred, e.g. baseline observations carried forward, above random imputation of missing outcomes.

The studies varied in the use of statistics and reporting of the effect sizes. We identified six types of reported effect measures: 1) baseline and follow-up data per group; 2) data of change within each group; 3) follow-up status per group; 4) estimates of difference of change between groups; 5) numbers and fractions of participants who reached behaviour goals at follow-up; and 6) standardized effect size between groups (e.g. Cohen's d). Whenever the data allowed, we made adjustments for baseline status. Sample size for each outcome and time-point were recorded in case of attrition or exclusion. Positive effect sizes indicated that the intervention group had a better outcome than the control group. When declining values of a measure indicated a positive effect (e.g. total fat), we reversed the effect size in order to report a beneficial intervention effect. If a study reported both physical activity and diet outcomes, we treated them as separate outcome reports in the analyses. We halved the group sizes to avoid double counting of participants and underestimating the variance associated with each effect size. Earlier studies also used this adjustment [9, 13].

Data synthesis and analytic strategy

The results from the PA and diet trials were standardized and calculated at two time-points if available; and hereafter referred to as short and long term results. Statistical approaches were used to re-express odds ratios (from dichotomous data) as standardized mean differences allowing dichotomous and continuous data to be pooled together (Hedges' $g = (m_i - m_c)/sd_{ic}$). Additional file 1 describes how the overall estimate of effect was calculated as a weighted average of the intervention effects from each trial. The Stata package `metan` was used to produce d and SE_d, and forest plots, and estimates of the pooled effect and heterogeneity index I^2. It was not likely that all our included studies had the same true effect size as they used a number of different outcome measures and

intervention design. Thereforee, the random-effects model was considered the most correct choice. We performed meta-analyses and compared the separate effect estimates of both diet- and PA trials at short and long term. The results were overlapping and comparable in effect size and with overlapping confidence intervals (Cis) (Table 1). We assumed that the target behaviour would not account much for the between-study heterogeneity, as previously shown in another review [9].

We applied a meta-regression using the Stata-package metareg to investigate sources of heterogeneity. In this analysis, the potential predictors were bias, study characteristics and BCTs. Studies were not excluded due to high risk and/or unclear risk of bias. Instead, we explored the effects of the bias by entering each bias as independent variables in the meta-regression analyses. After checking the impact of biases with three categories, unclear and high risk of bias were merged into one category (=1) as opposed to low risk of bias (=0) with negligible alteration of results. IBM SPSS Statistics was used to record the meta-data and prepare for the meta-analyses in Stata 14. We assessed possible publication bias by visually inspecting the funnel plots from the Stata meta-bias command.

Results

Studies included and intervention characteristics

Forty-eight studies met our inclusion criteria and were eligible for the meta-analyses, yielding a pooled population of 11 183 participants (see Flow Chart Fig. 1 from 46 individually RCTs and two cluster RCTs [38–85]. The duration of the interventions and frequency and time of data collection varied across studies. Baseline, 6 months and 12 months were the most common time points for data collection in the 48 studies. 73% of all the interventions ended by 3 to 6 months. The duration of the interventions varied from 12 weeks to 240 weeks for PA, and from 12 weeks to 72 weeks for the diet interventions. Twenty-four studies collected data at 12 months and/or at a later time point. Twelve months was the last follow-up for 14 of these studies. Last follow-up was 240 weeks (5 years). (For the complete presentation of study and intervention characteristics see Additional files 2 and 3).

From 48 studies, we identified 35 trials reporting PA and 26 reporting diet behaviour. These trials produced a total of 82 outcome reports for diet and PA; 50 at short term and 32 at long term (see studies and domains at short and long term, Table 1 and Figs. 2 and 3).

Effect of physical activity and healthy eating interventions at short and long term

Table 1 reports the results from stratified meta-analyses of PA and diet outcomes at both short and long term, as well as combined. The forest plots in Figs. 2 and 3 present effect size with 95% CI for each of the outcome reports and the pooled effect sizes from short ($n = 50$) and long term ($n = 32$) reports, respectively. The estimated effect sizes were modest (0.19-0.41). The 95% CIs overlapped and showed similar effects for PA and diet, justifying pooled analyses at short and long term. It became apparent that the pooled effect size from long term (0.24) was inferior to that of short term (0.37), although the 95% CIs overlapped (0.15-0.33 and 0.26-0.48). The indexes of heterogeneity revealed strong heterogeneity for short term outcome reports ($I^2 = 71\%$, $p < 0.0001$) and a moderate heterogeneity for long term outcome reports ($I^2 = 59\%$, $p < 0.0001$).

Bias, BCTs and other study characteristics

The Additional file 4 shows the risk of bias assessed for each of the included studies. In the eighteen studies using an objective measurement of effect, we assessed the risk for blinding of outcome assessment bias as low. This was often a PA monitoring device, e.g. an accelerometer. Most studies reported intention-to-treat analyses using "baseline observation carried forward" as a method to handle missing data from early intervention discontinuation. A few studies applied random imputation methods. High risk of attrition bias was often due to lack of information about dropouts and imbalanced attrition between the intervention- and control group. In two cases, risk of attrition bias was low at

Table 1 Summary effects of behaviour change of interventions in a meta-analysis of 48 RCTs 2007-2014

Time	Short term	Long term	Short + long term
Response measure	ES 95% CI	ES 95% CI	ES 95% CI
Physical activity	0.36 (0.24,0.47)	0.25 (0.13,0.38)	0.31 (0.23,0.40)
35 trials	30 reports	17 reports	47 reports
Diet	0.41 (0.20,0.62)	0.19 (0.07,0.31)	0.29 (0.16,0.42)
26 trials	20 reports	15 reports	35 reports
PA + Diet	0.37 (0.26,0.48)	0.24 (0.15,0.33)	
61 trials	50 reports	32 reports	82 reports

Abbreviations: RCT: randomized controlled trial; ES: effect size; CI: confidence interval; PA: physical activity

Results from a systematic review of 48 RCTs of behaviour change interventions with ≥ 12 weeks' duration, published from January 2007 to October 2014 for adults (mean age ≥ 40 years and with a mean BMI ≥ 30) according to type of behaviour and time of data collection ($p < 0.0001$). Short term represents outcome reports at ≤ 6 months in time, and long term represents reports at ≥ 12 months

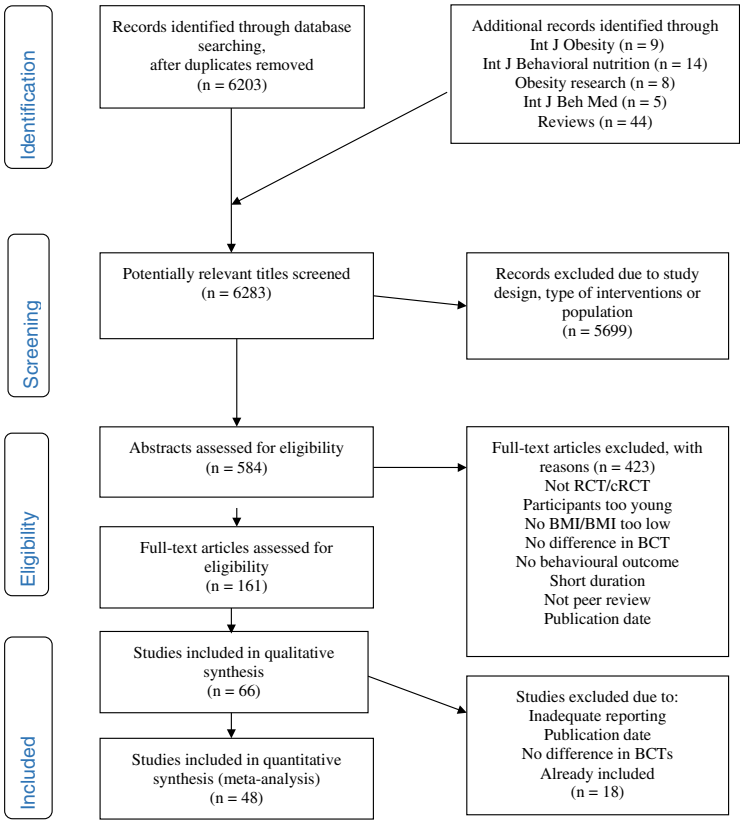

Fig. 1 PRISMA Flow Diagram for the inclusion of studies in a systematic review of physical activity and healthy eating interventions for overweight and obese adults from January 2007 to October 2014

short term, but high at long term due to an unbalanced dropout. High risk of reporting bias was associated with a significant positive intervention effect at short, but not at long term, explaining 18% of the variance of results, as demonstrated in Table 2 and Additional files 6 and 7.

When we started to code the BCTS, three researchers first coded five studies in cooperation in order to develop a joint understanding and coding practice. Thereafter GBS coded the remaining 43 studies individually whilst EM and TB individually coded 50% each. Fifty-four of 93 possible BCTs were identified as present in the intervention group, and not the control group by two researchers (see Additional file 5). Disagreement was resolved through discussions between two coders or, in two cases, by consulting the third coder. The mean kappa inter-rater agreement coefficient was 0.46 (range: 0.08 to 0.76) with an overall agreement between coders of 82% whether a BCT was present or not (range: 62 to 93%). Three of the BCTs were rated with high inter-rater reliability (>0.70) and nine reached medium interrater reliability (0.50-0.70). The remaining 17 BCTs had low interrater reliability (<0.50). In order to obtain statistical power, we included BCTs identified in a minimum of five studies in the meta-regression analyses. This left 29 BCTs for analyses. Additional files 6 and 7 presents the frequencies of the 29 BCTs, and measure of kappa and meta-regression analysis of effect.

The BCTs goal setting of behaviour and self-monitoring of behaviour were associated with positive intervention effect at both short and long term, as shown in Tables 2 and 3. Borderline significant evidence revealed that feedback on behaviour, feedback on outcome of behaviour, and demonstration of the behaviour were associated with successful interventions at short term. The BCT exploring the pros and cons of behaviour change was negatively associated (Table 2). The multiple meta-regression analyses also revealed that the BCT goal setting of behaviour and the

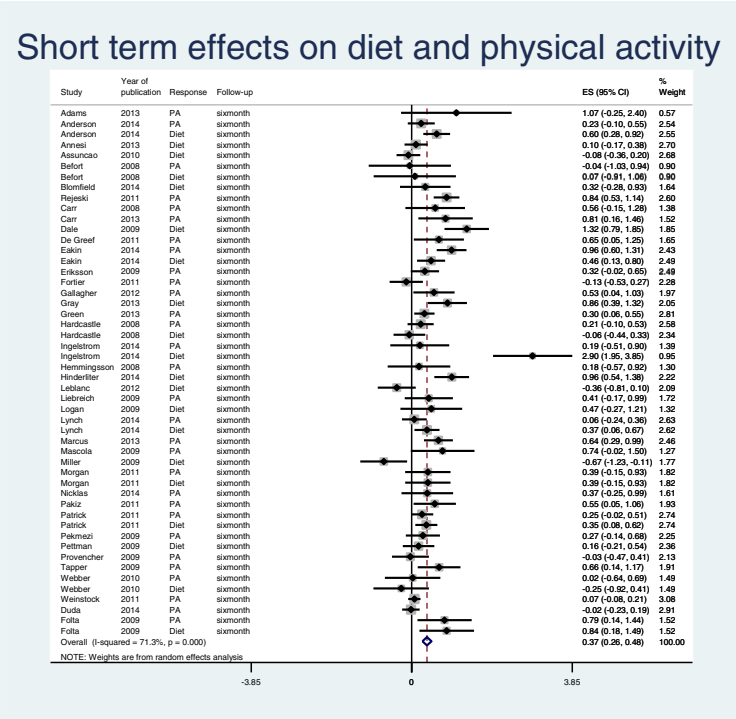

Fig. 2 Forest plot and meta-analysis of 50 outcome reports at short term (≤ 6 months) from diet and physical activity interventions for overweight and obese adults from January 2007 to October 2014

presence of reporting bias significantly predicted between-study variation, explaining 58.8%. However, strong inter-correlation existed between goal setting of behaviour (BCT 1.1) and self-monitoring of behaviour (BCT 2.3) (Chi squared = 33, df = 1). Therefore, we substituted BCT 1.1 with 2.3, in the final step of the regression analysis. Self-monitoring of behaviour was also significantly associated with intervention effect (b = 0.355; 95% CI: 0.128 to 0.582), but this model only explained 46.7% of the variance.

In addition to the BCTs goal setting and self-monitoring of behaviour, giving feedback on the outcome of behaviour, setting graded task, and adding objects to the environment, e.g. using a diet logbook, were associated with successful intervention reports at long term. As Table 3 demonstrate the BCTs problem solving, review of behaviour goals, and receiving general social support, were borderline significantly associated with positive results. In addition to the effect of using different BCTs, the multiple stepwise meta-regression analysis revealed that three study characteristics had independent explanatory power. Applying an autonomy supportive communication style in counselling, e.g. MI and SDT based interventions, the BCTs goalsetting of behaviour and receiving feedback on the outcome of behaviour, were all associated with trial effects, explaining 100% of the between study variation. Strong inter-correlation existed between feedback on outcome of behaviour (BCT 2.7) and goalsetting of outcome (BCT 1.3) (Chi squared = 30, df = 1). Therefore, we substituted both BCT 1.1 with 2.3 and BCT 2.7 with BCT 1.3 in the final step of the regression analyses. Goalsetting of outcome (BCT 1.3) was significantly associated with outcome effect (b = 0.149; 95% CI: 0.005 to 0.292), whereas self-monitoring of behaviour (BCT 2.3) only reached borderline significance (p = 0.059). This model still predicted 100% of the variance.

In the Introduction, we argued that SDT based interventions often use MI as a person-centred communication style to promote internal and autonomous motivation for change. However, when we compared all theory-or model-based trials with other trials, we found no evidence, neither at short or long term, that theory-based interventions were associated with between study effects. We did not identify any associations between treatment effects and 1) using objective versus self-reported data; 2) being in a community or workplace setting versus primary care

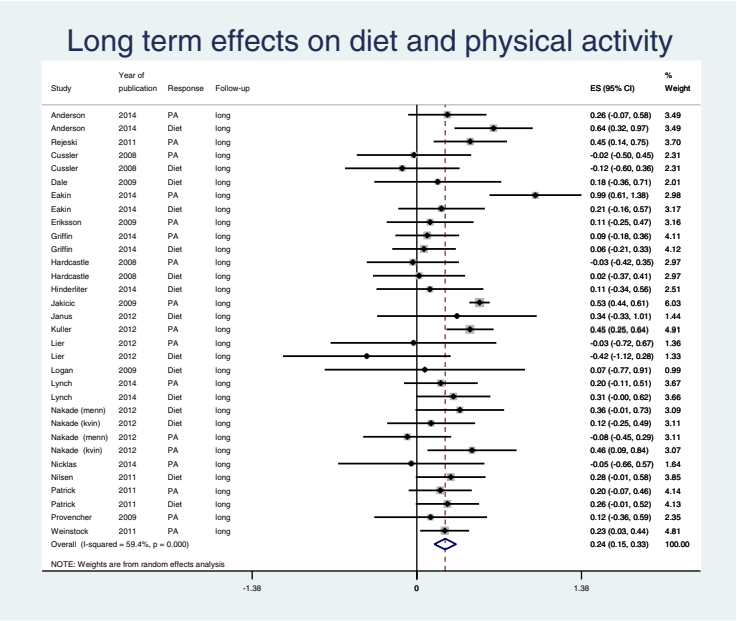

Fig. 3 Forest plot and meta-analysis of 32 outcome reports at long term (≥ 12 months) from diet and physical activity interventions for overweight and obese adults from January 2007 to October 2014

Table 2 Results from meta-regression analysis of 50 short term outcome reports of PA and diet interventions

	Simple meta-regression[a]				Multiple meta-regression[b]		
Study characteristics	b	95% CI	P value	Adj. R^2 %	b	95% CI	*P* value
BCT 1.1 Goal setting behaviour[c]	0.480	(0.257, 0.705)	<0.001	49.2	0.440	(0.225, 0.655)	<0.001
BCT 2.2 Feedback on behaviour[c]	0.219	(−0.040, 0.479)	0.096	4.4			
BCT 2.3 Self-monitoring of behaviour[c]	0.398	(0.164, 0.632)	0.001	35.3			
BCT 2.7 Feedback on outcome of behaviour[c]	0.243	(−0.040, 0.527)	0.091	12.0			
BCT 6.1 Demonstration of the behaviour[c]	0.244	(−0.035, 0.523)	0.085	11.9			
BCT 9.2 Pros and cons[c]	−0.252	(−0.542, 0.038)	0.087	4.8			
High and unclear risk of reporting bias[d]	0.670	(0.100, 1.240)	0.022	18.5	0.530	(0.257, 1.034)	0.040
Number of BCTs unique in intervention group[e]	0.033	(0.008, 0.059)	0.012	23.8			
Source of delivery[f]							
No health professionals/unclear	0.000	reference					
Other health professionals	−0.201	(−0.550, 0.148)	0.252				
Health professionals trained in behaviour change	−0.283	(−0.607, 0.040)	0.085	6.5			
Adj. R^2 %					58.8		

Abbreviations and symbols: BCT behaviour change technique, *PA* physical activity, *b* estimated meta-regression coefficient, *CI* confidence interval *Adj. R^2* adjusted proportion of between study variance explained by predictors

[a]Simple linear meta-regression of pooled estimates of 30 physical activity and 20 diet intervention's outcome reports. Only predictors with significant or borderline significant effects are reported; [b]Multiple linear meta-regression: results after stepwise backwards elimination from model with all significant predictors included. Only effects with $p < 0.05$ are retained in the model. [c]The difference of BCTs between intervention and control group contains this BCT, compared to studies not having this difference. [d]High and unclear risk of reporting bias versus low risk; [e]The number of unique BCTs in the intervention group as compared with the control group; [f]Source of delivery: competence of the counsellor

Table 3 Results from meta-regression analysis of 32 long term outcome reports of PA and diet interventions

	Simple meta-regression[a]				Multiple meta-regression[b]		
Study characteristics	b	95% CI	P value	Adj. R^2 %	b	95% CI	*P* value
BCT 1.1 Goal setting behaviour[c]	0.228	(0.056, 0.400)	0.011	38.5	0.175	0.043, 0.307	0.011
BCT 1.2 Problem solving[c]	0.161	(−0.005, 0.327)	0.057	25.1			
BCT 1.3 Goal setting outcome[c]	0.256	(0.095, 0.416)	0.003	53.2			
BCT 1.5 Review behaviour goals[c]	−0.319	(−0.678, 0.040)	0.078	19.8			
BCT 2.3 Self-monitoring of behaviour[c]	0.184	(0.009, 0.360)	0.040	30.8			
BCT 2.7 Feedback on outcome of behaviour[c]	0.249	(0.085, 0.412)	0.004	43.8	0.145	0.021, 0.269	0.024
BCT 3.1 Social support (unspecified)[c]	0.192	(−0.011, 0.394)	0.063	21.6			
BCT 8.7 Graded tasks[c]	0.203	(0.043, 0.363)	0.014	37.1			
BCT 12.5 Adding objects to the environment[c]	0.182	(0.010, 0.354)	0.039	12.7			
Method based[d]							
MI/SDT	0.000	reference					
ACT/CT/HAES/Mindful/other	−0.303	(−0.500, −0.105)	0.004				
Unclear	−0.199	(−0.372, −0.026)	0.026	57.5	−0.170	−0.294, −0.045[g]	0.009
Number of BCTs unique to the intervention group[e]	0.028	(0.012, 0.044)	0.001	54.3			
Total number of BCTs in intervention + control group[f]	0.030	(0.014, 0.046)	0.001	61.3			
Adj. R^2 %					100.0		

Abbreviations and symbols: BCT Behaviour change technique, *PA* physical activity, *ß* estimated meta-regression coefficient, *CI* confidence interval, *Adj. R^2* adjusted proportion of between study variance explained by predictors

[a]Simple linear meta-regression of pooled estimates of 17 physical activity and 15 diet intervention's outcome reports. Only predictors with significant or borderline significant effects are reported; [b]Multiple linear meta-regression: results after stepwise backwards elimination from model with all significant predictors included. Only effects with $p < 0.05$ are retained in the model; [c]The difference of BCTs between intervention and control group contains this BCT, compared to studies not having this difference. [d]Method-based interventions comparing MI or SDT based interventions with Acceptance and commitment therapy (ACT), Cognitive therapy (CT), Health-at-every-size (HAES) approach, Mindful based intervention or other methods, versus no method mentioned; [e]The number of unique BCTs in the intervention groups as compared with the control group; [f]The total number of BCTs in intervention and control group; [g]The variable is dichotomized in the multiple meta-regression analysis to MI/SDT versus all others

or hospital; 3) receiving an individual or group based intervention; and 4) promoting behaviour change in one domain versus two (both diet and PA).

Publication bias

We assessed publication bias by inspection of funnel plots, see Additional files 8 and 9. The funnel plot of short term reports showed a fairly symmetrical distribution, demonstrating low risk of publication bias. The funnel plot of long term reports was asymmetrical, and revealed an over-representation of publications of small studies with low effects.

Discussion

Main results

The present review shows that behaviour change interventions for diet and PA are modestly effective both at short and long term, and that the heterogeneity between studies is high, especially at short term. However, we have revealed study characteristics that explain most of the variance between studies. In particular, several BCTs that facilitate self-regulation of behaviour explain intervention effects, e.g. the BCTs goalsetting of behaviour and self-monitoring of behaviour. Interventions that emphasize a person-centred and autonomy supportive communication style, as MI, SDT and other autonomous based interventions, are associated with effects at long term. Facilitating self-regulation and sustained positive motivation are previously identified as two important themes in theoretical explanations for maintenance of behaviour change [5].

Strengths and limitations

In the present review, we have applied an internationally validated taxonomy identifying BCTs [6]. Two researchers coded risk of bias and BCTs independently and came to an agreement through discussion. We included only RCTs and adjusted for baseline status whenever possible. By applying a search strategy formerly used with high utility [10], we maintain that a comprehensive collection of relevant papers was found. We have complied with a predefined protocol published at the start of the study. Statistical methods were in line with formerly advocated methods [9]. We also checked for correlations of BCTs, a previous methodological weakness pointed out by Peters and colleagues [35]. Unlike previous reviews, we have collected outcome reports at two points in time in order to differentiate between short and long term intervention

effects. However, we do acknowledge that 12 months is a rather short timeframe for evaluating long term maintenance.

Modest inter-rater reliability was obtained in coding despite completing an online education and certification. The descriptions of the interventions' BCTs and other study characteristics were at times limited and lacked precision, even after checking the protocol article. Only a minority of the studies reported the fidelity. We do not know to what extent reported interventions were implemented as planned. The results of this review are also limited by the fact that the inclusion of RCTs stopped in October 2014. The methodological procedures, involving several researchers, have been thorough and time consuming. We have updated our search once but a second update proved impossible due to time restrictions.

Our findings compared with other studies

Our pooled effect estimation of interventions for PA at short term are comparable to some previous reviews [9, 86], higher than one [11, 12], and lower than another [87]. Our pooled effect for diet interventions was lower than in one comparable study [11]. As far as we are aware no reviews using the BCTTv1 [86, 88, 89] have performed meta-analyses combining healthy eating and PA interventions among overweight and obese adults, and used meta-regression to examine differences in effect size as a function of BCTs or other study characteristics. Previous reviews have used either the 26 or the 44 BCT taxonomy [8, 9], on various target populations, behaviours, and used different meta-analytic strategies. Unlike these, we only recorded BCTs present in the intervention and absent in the control condition. Therefore, our ability to compare our findings with former studies was somewhat limited.

However, results from this study showed that helping participants to define a goal, e.g. eating five fruit and vegetables per day, or to monitor the behaviour, for instance in a log book, were independently associated with better intervention effects. These results are supported by earlier studies for the BCT goalsetting of behaviour [13, 89], and self-monitoring of behaviour [9, 10, 90]. Our analyses suggest that these BCTs also affected long term results. As expected, having more BCTs unique to the intervention group, and not the control group, were associated with larger effect sizes at both short and long term. A previous study have illustrated how the content of the control condition, e.g. waiting list, usual care or alternative treatment may influence the effect size [86]. Using BCTs that help the participant to identify realistic outcomes of a new behaviour, e.g. reduce CVD risk factors, or when counsellors give feedback on results, e.g. praising efforts, were independently associated with intervention effect at long term. The effect of outcome feedback has also been reported by Lara and colleagues [13], and contrasted in another study which demonstrated a negative effect [11]. Applying the BCTs setting graded tasks and adding objects to the environment, e.g. using a mobile app to register PA, were independently associated with intervention success at long term. As far as we know, no previous reviews which used any of the taxonomies [6–8] have associated these BCTs with intervention effects, except one study which reported a negative impact of using graded tasks [90].

Using the BCTs problem solving (e.g. to identify barriers or facilitators for change), review of behaviour goals, and receiving social support (e.g. from staff or other participants) were borderline significantly associated with positive outcomes at long term. Problem solving and planning of social support have previously been associated with effects in diet and smoking cessation counselling [13, 91]. Theoretical explanations and self-regulation models for behaviour change maintenance recommend the use of these BCTs [5, 92]. The BCT to explore the pros and cons argument of change during the intervention were borderline significant and negatively associated with the intervention effect. This is not surprising. Exploring ambivalence may improve motivation among people not ready for behaviour change, but can actually hamper motivation when the client is ready for change. In these cases a more action oriented counselling seems more beneficial [93].

In line with earlier studies [16, 88], we found no evidence that the mode of intervention delivery was associated with intervention effects. This finding supports the notion that a wide range of providers can deliver effective diet and physical activity interventions, both professionals and lay people. Unlike previous findings we found no effect of treatment settings [10]. Increasing the number of total BCTs was associated with positive intervention results as also confirmed by other studies [13, 86].

There were no evidence, neither at short term nor at long term, that theory-based interventions were associated with positive results. It was beyond the scope of this review to consider if and how the theory was applied in the intervention design, e.g. if theory relevant constructs or predictors were linked to intervention techniques [15, 94]. Unlike Wilson and colleagues we did not identify any associations between promoting behaviour change in one domain versus two (diet plus PA) and trial effects [95].

Behaviour change initiation and maintenance

Meta-regression analyses revealed that person-centred methods as in Motivational Interviewing, SDT and other autonomous supporting interventions were associated with maintenance of change at ≥12 months. Previously, only a few PA interventions have reported positive intervention effect at more than 12 months [16, 30, 96]. Dietary

interventions have showed positive changes at 6 to 19 months [16]. Our findings suggest that setting a goal for behaviour change and to monitor the new behaviour are effective in helping people to both initiate change and to maintain the change. In line with theoretical explanation of maintenance, the focus will change from expectations of future outcomes to experiences with results over time; the cost and limitation of self-regulation, setbacks, and relapses [5]. BCTs like goalsetting of outcome, setting graded tasks, and getting feedback on outcome, highlights the results achieved and the possible satisfaction with the new behaviour. If counselling is performed in a person centred and autonomous supporting manner, the participants' self-regulatory strength may be renewed by developing a genuine appreciation of healthy food, and development of autonomy (sense of choice, feeling volitionally), and internalization of the new behaviour into the person's perceived values, aspirations, and autonomous self-regulations [31].

The results from the present review supports two theoretical themes important in maintenance of change [4, 5]; BCTs facilitating behaviour self-regulation, e.g. skills and functional aspects of behaviours ("how to"), combined with a communication style that addresses the underlying nature of motivation ("the why") in order to maintain the new behaviour over time. These perspectives are not opposites, but complement each other. Without the first, there would be lack of competence. Without the second, there is lack of meaning, value, and satisfaction of psychological needs.

Can BCT research inform counselling practice?

Efforts to identify effective BCTs using taxonomies have been criticized for ignoring the manner by which the BCTs are presented. Hagger and colleagues argue that the interpersonal style represents a unique set of techniques and should be included in the taxonomies [97]. When coding the MI, SDT or ACT based interventions for this review we experienced a lack of relevant techniques, and we were unable to code e.g. eliciting the "promoting participants own reasons for change"; "unconditional personal regard"; "provision of choice" and; "in an autonomy supportive manner". Additionally, in this review we had to exclude one study because it was impossible to code the difference in "restrictive" and "positive" messages in counselling, although we felt that this was a rather important difference [98]. We should also acknowledge Jane Ogden's warnings that the promotion of BCTs as strict techniques may hamper professional variability and turn professionals into technicians [99]. The present study supports the importance of applying the techniques with professional respect and empathy.

Conclusions

There are similarities, but also differences in effective BCTs promoting change in healthy eating and physical activity and BCTs supporting maintenance of change. The results support the use of goal setting and self-monitoring of behaviour when counselling overweight and obese adults. Several other BCTs as well as the use of a person-centred and autonomy supportive counselling approach seem important in order to maintain behaviour over time.

Additional files

Additional file 1: Computation of standardized mean differences (DOCX 14 kb)

Additional file 2: 48 physical activity and diet studies included in review (DOCX 39 kb)

Additional file 3: Intervention characteristics of 48 PA and diet studies included in review (DOCX 44 kb)

Additional file 4: Risk of bias in 48 included studies by first author (DOCX 32 kb)

Additional file 5: BCTs unique to the intervention and not in the control group coded by The behaviour change technique taxonomy. (DOCX 29 kb)

Additional file 6: Table 4. Results from simple linear meta-regression analysis of short term reports of PA and diet interventions. (DOCX 35 kb)

Additional file 7: Table 5. Results from simple linear meta-regression analysis of long term reports of PA and diet interventions. (DOCX 33 kb)

Additional file 8: Figure 4. Funnel plot short term. (DOCX 15 kb)

Additional file 9: Figure 5. Funnel plot long term. (DOCX 15 kb)

Abbreviations

BCT: Behaviour change technique; CI: Confidence interval; CT: Cognitive therapy; ES: Effect size; HAES: Health-at-every-size; MI: Motivational interviewing; NCD: Non-communicable disease; PA: Physical activity; RCT: Randomized controlled trial; SDT: Self-determination theory; se: standard error; SMD: Standardized mean difference

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Availability of data and materials

All data generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

GBS designed the protocol, collected and analysed data, and drafted the manuscript. EM took part in designing the protocol, collecting and analysing data, and drafting the manuscript. TB and GW took part in data collection. GEE supervised the data analyses. GBS, EM, GEE, TB, GW gave inputs on several drafts of the manuscript. All authors critically revised the final manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate
Not applicable.

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Additional file 1 Computation of standardized mean differences

The overall estimate of effect was calculated as a weighted average of the intervention effects from each trial using statistical methods as follows:

Let M denote the mean, t the time of measurement (0 = baseline), and i the treatment group (i = 1, 2 for control and treatment, respectively). According to the six types of effect measures reported the following effect measures were recorded for i = 1, 2:

1) With M_{ti}, S_{ti}, and n_{ti} at t = 0 and at some t > 0 the mean differences $D_{ti} = M_{ti} - M_{0i}$ could be calculated, but the standard deviation of the difference could not be. Thus the estimates at t > 0 were chosen and recorded, i.e. M_{ti}, S_{ti} and n_{ti}; 2) Here the mean changes until t > 0, D_{ti} , and the standard deviations S_{ti} for the changes were available directly and recorded; 3) In this case M_{ti}, S_{ti} and n_{ti} at time t > 0 were recorded directly; 4) If D denotes the estimate of difference of change between the two groups, we estimated the standardized mean difference, d, and its standard deviation, SE_d, using the theory in Borenstein and collegues [1], i.e. by formulae (4.18) and (4.20) [1]:

$$\mathrm{d} = \frac{D}{S_{within}} \qquad \text{with} \qquad S_{within} = S_{pooled} = \sqrt{\frac{n_1 n_2}{n}} SE_D$$

and $SE_D = \sqrt{V_D}$ with $V_D = \frac{n_1+n_2}{n_1 n_2} + \frac{d^2}{2(n_1+n_2)}$

5) With the count of individuals that obtained their goal at time t > 0, also denoted by M_{it}, these were recorded and their estimated standard deviations calculated as $S_{it} = \sqrt{[M_{ti}(n_{ti}-M_{ti})/n_{ti}]}$ and recorded; 6) The standardized effect size and its standard deviation, d and SE_d, was recorded directly.

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Additional file 2: 48 physical activity and diet studies included in review

First author & Publication year	Design Name of study	Participant information Health status Mean age Mean BMI Gender (%female) Ethnicity	Intervention + Control group sample size	Total retention rate at end of study	Time points data collection and last follow-up	Outcomes collected	Outcome(s) included in review (S) = Self-report (O) = Objective PA= Physical activity
Adams 2013	RCT	Inactive overweight Age 37 BMI 30 85% female 35 % non -white	Int N 10 Con N 10	90 %	0, 6 months =24 weeks	Steps/day	PA: Steps/day (O)
Anderson 2014	RCT	Overweight/obese Age 64 BMI 31 74% men 100 % white	Int N 163 Con N 166	93%	0,6,12 months = 48 weeks	Weight, waist circumference, blood pressure, fasting cardiovascular biomarkers, glucose metabolism variables, physical activity, diet, alcohol consumption	PA: Steps/day (O) Diet: Fat % (S)
Annesi 2013	RCT	Sedentary adults Age 44 years BMI 39,8 81% female 52% White 46% Black 2 % Other	Int N 101 Con N 99	86%	0,3,6 months = 24 weeks	Exercise, fruit and vegetable intake self-regulation, self-efficacy, mood	Diet: Fruit &Vegetable (S)
Assuncao 2010	RCT	Overweight/obese Age 40 BMI 34 89 % female	Int N 120 Con N 121	80%	0, 6 months = 24 weeks	Weight, BP, lipids and glucose levels, physical activity, diet	Diet: Fats (S)
Befort 2008	RCT	Obese African American women Age 44 BMI 40	Int N 21 Con N 23	77%	0,16 weeks	Weight loss, dietary outcome, physical activity, motivation, self-efficacy	PA: Min /week (S) Diet: Energy intake kcal /day (S)
Blomfield 2014	RCT	Overweight/ obese Age 47 BMI 33 100% men	Int N 53 Con N 52	81%	0,3,6 months = 24 weeks	Weight, dietary intake, portion size	Diet: Fat/day (S)
Rejeski 2011	RCT	Overweight/ obese with CVD or risk for CVD Age 67 BMI 33 66% Female 82 % White 17 % Black 1 % Other	Int N 98 Con 93	86%	0,6, 18 months = 72 weeks	400-m walk,, weight loss, level of physical activity, adverse events	PA: Moderate to vigorous /week (O)
Carr 2008	RCT	Sedentary, overweight/ obese Men & women Age 35 BMI 31	Int N 14 Con N 18	51%	0,16 weeks	Physical activity, fitness, anthropometric and body composition, metabolic measures	PA: Steps /day (O)
Carr 2013	RCT	Sedentary/ overweight Age 45	Int N 25 Con N 24	81%	0,12 weeks	Sedentary and physical activity, heart rate, blood pressure, height, weight, waist circumference, per cent body fat,	PA: Sedentary time/day (O)

Additional file 2: 48 physical activity and diet studies included in review

	Pedal@Work	BMI 32 90% Female 70% Non-Hispanic White				cardiorespiratory fitness, fasting lipids	
Cussler 2008	RCT	Females after a 4-month weight loss treatment Age 48 BMI 31	Int N 66 Con N 69	82%	0, 12 months = 48 weeks	Weight loss maintenance, anthropometric and body composition, physical activity, diet	PA: Exercise energy expenditure (kcal/day) (S) Diet: Energy intake (kcal/day) (S)
Dale 2009	RCT	Overweight insulin resistant Age 46 BMI 34 67% female 100 % Caucasian	Int N 56 Con N 23	78,5%	0,4,8,12,24 months = 96 weeks	Weight loss, anthropometric and body composition , blood pressure, fasting glucose, lipids, insulin and aerobic fitness, dietary intake	Diet: Total fat (S)
De Greef 2011	RCT	Diabetes type 2 Age 67 BMI 30 30 % Female	Int 1 N 21 Con N 67	96%	0,12 weeks	Pedometer-determined steps/day, physical activity , weight, body mass index, waist circumference, total cholesterol, fasting glucose, HbA1c	PA: Steps/day (O)
Eakin 2014	RCT	Diabetes type 2 Age 58 BMI 33 44% Female 68% born in Australia 87 % Caucasian	Int N151 Con N151	77%	0,6,18,24 months =96 weeks	Weight, physical activity, HbA1c, dietary energy intake, diet quality, waist circumference, lipid levels, blood pressure	PA: Moderate to vigorous /week (O) Diet: quality (S)
Eriksson 2009	RCT The Swedish Bjørknes study	Risk of CVD Age 54 BMI 30 57% Female	Int N71 Con N 74	80 %	0,12,24,36 months =144 weeks	Anthropometrics, aerobic fitness, self-reported physical activity, blood pressure, metabolic traits	PA Total (S)
Fortier 2011	RCT The physical activity Counselling (PAC) trial	Sedentary Age 47 BMI 31 69 % Female 99 % Caucasian	Int N 61 Con N 59	82%	0,6,12,18, 25 weeks	Physical activity, quality of life, metabolic outcomes	PA: Activity counts per minutes (O)
Gallagher 2012	RCT Healthy Eating and Exercise Lifestyle Program	Overweight or obese with CHD and/or Diabetes type 2 58% Male Age 63 BMI 31 79 % Caucasian	Int 83 Con 65	91%	0,12 weeks + 6, 12 months = 48 weeks	Weight loss, waist circumference and exercise, self-efficacy	PA: Duration, min/week (S)
Gray 2013	RCT	Overweight/obese men Age 47 BMI 35	Int N 51 Con N 52	84%	3, 6, 12 months = 48 weeks	Weight, waist circumference, blood pressure, body composition, physical activity, diet, alcohol consumption, psychological outcomes, qualitative data	Diet: Fruit & vegetable (S)
Greene 2013	RCT	Overweight/obese 78 % over 40 years' old 93 % overweight/obese 79% Female 93% Caucasian 7% Other	Int N 137 Con N 125	68%	0,3,6 months = 24 weeks	Physical activity, weight, cholesterol, and triglycerides	PA: min/week (O)
Griffin 2014	The ADDITION-Plus RCT	BMI 32 Age 59	Int N 239 Con N 239	94%	0,12 month =48 weeks	Physical activity energy expenditure, fruit and vegetable intake, medication adherence, smoking status	Diet: C vitamin plasma (0)

Additional file 2: 48 physical activity and diet studies included in review

		62 % men 97% White					PA: Energy expenditure kJ/day (O)
Hardcastle 2008	RCT	Overweight/ obese BMI 34 Age 51 67 % Female	Int N 203 Con N 131	65%	0.6, 18 months =72 weeks	Diet, physical activity, body mass index, weight, blood pressure and cholesterol	Total PA (S) Diet: Fruit & vegetable (S)
Ingelström 2014	RCT	Obstructive sleep apnea syndrome and overweight Age 55 BMI 35 20 % Female	Int 36 Con 30	72%	0,6 months =24 weeks	Diet, eating behavior, weight, BMI, waist circumference, PA, sedentary time .	PA: Steps (O) Diet: Vegetable /week (S)
Hemmingsson 2008	RCT	Obese Age 43 BMI 42 79 % Female	Int N 28 Con N 27	76%	0,18 weeks	Steps /day	PA Steps /day (O)
Hinderliter 2014	RCT	Overweight with high BP Age 52 BMI 33 67 % Female 60 % White 39 % Black 1% Asian 3 % Hispanic	Int N 49 Con N 49	86%	0, 4, 12 months =48 weeks	BP, weight, dietary intake, exercise habits, medication	Diet: Total kcal/day (S)
Jakicic 2009	RCT The Look AHEAD trial	Diabetes type 2 Age 58 BMI 36 59% Female 36% Non-Caucasian	Int N 1118 Con N 1103	85%	0, 12 month = 48 weeks	Fitness, physical activity	PA: Leisure-time kcal/week (S)
Janus 2012	RCT	Risk of Diabetes type 2 Age 65 BMI 31 66% Female	Int N 49 Con N 42	87%	0, 12 months = 48 weeks	Anthropometric, laboratory tests, psychosocial, diet, physical activity depression and anxiety	Diet: Total fat % (S)
Kuller 2012	RCT The Women on the Move through Activity and Nutrition (WOMAN) study	Women at risk for CVD Age 57 BMI 31 88% Caucasian	Int N 253 Con N 255	90%	0, 18,36,48 months =192 weeks	Laboratory, subclinical and anthropometric measurements, drug treatment, weight loss, diet, physical activity	PA: Leisure time MET h/week (S)
Leblanc 2012	RCT	Overweight/ obese women Age 42 BMI 36	Int N 48 Con N 46	87,7%	0,4 6 months =24 weeks	Anthropometric measurements, dietary intakes, eating patterns	Diet: Energy intake (kcal) (S)
Liebreich 2009	RCT	Diabetes type 2 Age 54 BMI 34 59% Female	Int N 25 Con N 24	90%	0,12 weeks	Physical activity, several social cognitive measures, e.g. self-efficacy, self-regulation, observational learning, social support	PA: Moderate to vigorous min /week (S)
Lier 2012	RCT	Obese (Bariatric surgery) Age 42 BMI 45	Int N 49 Con N 50	78%	0, 12 months = 48 weeks	Anthropometric measurements, diet, anxiety, depression, quality of life	PA: Min/week (S) Diet: Meals each day (S)

Additional file 2: 48 physical activity and diet studies included in review

		73% Female					
Logan 2010	RCT	Coronary heart disease Age 57 BMI 30 20 % Female	Int N 19 Con N 18	60%	0,6,12 months =48 weeks	Demographic variables, diet, smoking status, weight, height, blood pressure and sample	Diet: Mediterranean diet score (S)
Lynch 2014	RCT	Survivors of colorectal cancer Age 66 BMI insufficiently reported 46% Female	Int N 205 Con N 205	79%	0, 6, 12 months =48 weeks	Demographic variables, anthropometric measurements, diet, physical activity, cancer-related fatigue, health-related quality of life	PA: Total sedentary time h/day (S) Diet: Total fat % of kJ intake (S)
Marcus 2013	RCT The Seamos Saludables Study	Inactive Latinas Age 40 BMI 30 100 % Female	Int N 132 Con N 134	86%	0,6,12 months =48 weeks	Physical activity	PA: Moderate to vigorous min /week (S)
Mascola 2009	RCT	Overweight/obese Age 43 BMI 35 92% Female 77% White	Int N 14 Con N 12	?	0,3 months =12 weeks	Physical activity/week, cardiorespiratory fitness, and depression	PA: Hours/week of moderate-equivalent (S)
Miller 2009	RCT	Diabetes type 2 Age 54 Weight mean 106 kg 64 % Female 77% Caucasian	Int 32 Con 36	76%	0,3 months =12 weeks	Weight, anxiety/depression, outcome expectations, nutrition and eating-related self-efficacy, eating behaviors (cognitive control, disinhibition, hunger), mindfulness	Diet: Energy (kcal) (S)
Morgan 2011	Cluster RCT The Workplace POWER (Preventing Obesity Without Eating like a Rabbit)	Male shift workers Age 44 BMI 30	Int N 65 Con N 45	81%	0,14 weeks	Weight, waist circumference, BMI, blood pressure, resting heart rate, physical activity, diet, physical activity and dietary cognitions	PA: Total MET minutes (S) Diet: Fruit servings/day (S)
Nakade 2012	RCT Saku Control Obesity Program (SCOP)	Overweight/obese Age 54 BMI 30 50 % Female	Int N 119 Con N 116	96%	0,12,24 months =96 weeks	Anthropometric and biological data, physical activity, diet and eating behavior, stages of change	Diet: Energy kcal/day (S) PA steps/day (O)
Nicklas 2014	RCT	Obese Age 70 BMI 33 76% Female 86% Non-Hispanic white 14 % Non-white	Int N 23 Con N 23	85%	0, 5,10 months =40 weeks	Body weight, physical activity, energy expenditure	PA: Steps/day (O)
Nilsen 2011	RCT	Risk of diabetes type 2 Age 47 BMI 37 50% Female	Int N 109 Con N 104	85%	0,3, 26 weeks, 18 months =72 weeks	Anthropometric and biological data, blood sample, diet quality, physical test	Diet: Smart Diet Score (S)
Pakiz 2011	RCT	Overweight breast cancer survivors Age 56 BMI 31 94% Non-Hispanic White	Int N 44 Con N 24	81%	0,16,48 weeks	Anthropometric and biological data, physical activity	PA: PA recall (S)
Patrick 2011	RCT	Overweight/ obese	Int N 224	70%	0,6,12	Anthropometric data, BMI, diet, physical activity	PA. Walking min/day (S)

Additional file 2: 48 physical activity and diet studies included in review

		Men Age 44 BMI 34 71% White non-Hispanic 18% Hispanic 12 % Others	Con N 217		months =48 weeks		Diet: Fruit & vegetable servings/day (S)
Pekmezi 2009	RCT Seamos Activas	Overweight/obese Latino/Hispanic women Age 41 BMI 47 % obese	Int N 45 Con N 48	87%	0,6 months =24 weeks	Physical activity, cognitive and behavioral processes of change, self-efficacy, social support, depression, access to nearby physical activity facility	PA: Moderate physical activity (S)
Pettman 2009	RCT	Metabolic syndrome Age 45 BMI 37 73% Female	Int N 103 Con N 50	91%	0,4 months =16 weeks	Anthropometric, physical fitness, diet, body composition, cardio-metabolic risk factors, fasting blood sample	Diet: KJ reduction (S)
Provencher 2009	RCT	Premenopausal overweight/obese women Age 42 BMI 30 93% White	Int N 48 Con N 48	74%	0,4,6 12 months =48 weeks	Eating behaviors, appetite sensations, metabolic and anthropometric variables, and physical activity levels	PA mean energy exp (S)
Tapper 2009	RCT	100 % Women Age 41 BMI 32	Int N 31 Con N 31	81 %	0,4,6 months =24 weeks	BMI, physical activity, mental health	PA: Bouts of 30 m /week (S)
Webber 2010	RCT	100 % Female Age 49 BMI 32 92% Caucasian	Int N 40 Con N 40	82%	0,4,16 months =64 weeks	Body composition , controlled and autonomous motivation, diet, PA, weight loss self-efficacy, depression	PA: Increase in PA (S) Diet: Decrease energy intake kcal/day (S)
Weinstock 2011	RCT IDEATel study	Ethnically diverse, medically underserved Medicare beneficiaries with diabetes 63% Female Age 71 BMI 32 White 50% Black 15% Hispanic 35%	Int N 837 Con N 813		0,3,6 months, 5 years =240 weeks	Hemoglobin A1c, social support, decline in PA and physical impairment, comorbidity, activities of daily living, diabetes self-care activities	PA: Diabetes self-care PA score (S)
Duda 2014	Cluster RCT	90% overweight /obese Age 89% over 30 72,9 % Female 28% Non-white	Int N 184 Con N 163	56%	0,3,6 months =24 weeks	Physical activity, health status, emotional well-being, anxiety, depression, quality of life, vitality, autonomy support, need satisfaction, intentions to be active, motivational regulations for exercise, BP, weight	PA: Moderate -vigorous min/week (S)
Folta 2009	Cluster RCT Strong Women–Healthy Hearts intervention	Sedentary midlife and older overweight/obese 100% Female Age 57 BMI 33	Int N 61 Con N 35	89%	0,12 weeks	Anthropometric data, diet, PA	PA: Steps (O) Diet: Energy intake kcal/day (S)

Abbreviations: RCT = randomized controlled trial. Int = Intervention grou. Con = Control group. BMI = Body Mass Index. PA= physical activity. S= Self-reported data. O= Objective measure.

Additional file 3 Intervention characteristics of 48 PA and diet studies included in review

First author of study	Intervention group	Control group	Source of delivery Treatment setting	Duration for intervention Intensity	Format	Theory mentioned in abstract, introduction or method section
Adams 2013	An adaptive physical activity intervention	A static physical activity intervention	Unclear Community, USA	24 weeks Email and text message communication every day and biweekly motivational prompts	Website Individual	
Anderson 2014	BeWEL programme	A weight loss booklet	Trained lifestyle counsellors Cancer screening clinics, NHS Scotland	48 weeks three, one hour, face to face visits with a lifestyle counsellor during the first three months (including spouse or friend when possible), followed by nine, monthly, 15 minute telephone consultations	Face to face Individual Telephone	
Assunco 2010	Nutritional care (dietetic prescription)	Usual care (individual consultations with nutritionist in public health system)	Nutritionists Nutrition Outpatient Clinic, Medical Teaching Hospital, Brazil	24 weeks Individualized nutritional care	Face to face Individual	
Anessi 2013	Cogn. behavioural exercise support + Cogn.beh. methods for nutrition change	Cogn.behavioural exercise support + stand. nutrition education	Certified YMCA wellness leaders Community, USA	24 weeks Individual exercise support 6 x 1 hour meetings Group based nutritional component 6 x1 hour meetings	Face to face Group Individual	Self-efficacy Theory Social Cognitive theory Theory of Self-regulation
Befort 2008	Behavioral weight loss program plus MI sessions	The same behavioral weight loss program plus four health education sessions	A doctorate-level psychologist and a masters-level counsellor or dietitian trained in MI Community health center Serving, USA	16 weeks 90-min weekly group sessions plus 4 x 30-min MI sessions	Face to face Group Telephone	
Blomfield 2014	Information resources with access to a website for self-monitoring of diet and exercise with individualized e-feedback	Waiting list	Research assistants using a standardized set of feedback sheets Community, Australia	12 weeks Email and 7 indiv. feedback sheets. Diaries reviewed weekly in the 1st month, fortnightly in the 2nd month and once in the 3rd month. DVD, Handbook, Support book	Website Individual	Social Cognitive Theory
Rejeski 2011	A physical activity program in conjunction with dietary weight loss	Successful aging education control	Cooperative Extension agents Community, USA	72 weeks Months 1 to 6 Intensive phase: 3x 90 minutes' group sessions and 1x 30 minutes' individual session per month. Months 7 to 18 Maintenance phase: 2 contacts each month (group session, telephone contact)	Face to face Group Individual Telephone	Social Cognitive Theory
Carr 2008	Internet-delivery of the Active Living Every Day (ALED program and workbook)	Maintain current behaviour	Licensed program administrators/ facilitators Community, USA	16-week A self-paced program using of interactive activities. Journal activity	Website Individual	Transtheoretical Model of Behavioural Change Social Cognitive Theory
Carr 2013	An intervention to reduce sedentary time	Maintain current behaviour	Unclear University worksite, USA	12 weeks A pedal machine connected to the PC during all working hours. Daily email messages to self-monitor, daily pedal time and daily steps on the website. Virtual competition for groups of intervention participants. Three motivational emails each week.	Website Individual Email	Social Cognitive Theory
Cussler 2008	A weight maintenance internet intervention	No contact (self-directed weight maintenance)	Study staff Community, Arizona area, USA	48 weeks Progress monitoring tools (body weight, physical activity, dietary intake, and "mind-body" logs), curriculum materials	Website Individual Group	

Additional file 3 Intervention characteristics of 48 PA and diet studies included in review

				and up-to-date dietary and physical activity information, and links to other websites of interest private & group mail Bulletins, Chat rooms, Support group		
Dale 2009	Dietary and exercise advice (modest and intensive level)	Usual diet and exercise routine	Experienced dietitian and physical activity instructor Community, New Zealand	16 weeks (with a 24 months follow-up) Individually designed advice. Seen weekly by researchers for weight measurements and a short dietary and exercise assessment. 8 and 12 month encouraging visits to discuss diet and PA	Face to face Individual	
De Greef 2011	Cognitive-behavioral therapy	Usual care from GP	Clinical psychologist with a background in behavior change strategies General practices, Belgium	12-weeks One 90-min group counselling session every three weeks	Face to face Group	
Eakin 2014	Telephone counselling	Usual care	Counsellor: least bachelor's level training in nutrition and dietetics; some also dual-degree in exercise physiology. One-month intensive training in study protocols and motivational interviewing Primary care, Australia	72 weeks 27 telephone calls over the 18 months (4 initial weekly calls; fortnightly calls for 5 months; monthly calls for 12 months)	Face to face Individual Telephone Workbook	Social Cognitive Theory
Eriksson 2009	Exercise sessions and diet counselling	Usual care + information about healthy behaviour	Physiotherapists, dietitian, physician Primary care, Sweden	12 weeks Exercise training and diet counselling 3 sessions/ week x 5, 6 follow-up meeting/ 1. year, 4/ 2. year, 2/3.year. Diet counselling once/year for 3 years	Face to face Group	Transtheoretical Model of Behavioural Change
Fortier 2011	Brief + intensive physical activity counselling	Brief physical activity counselling (2-4 min)	Physical activity counsellor, BSc in Human Kinetics, certified Fitness consultant Primary care, Canada	12 weeks 6 MI sessions over 3 months every 2 weeks, 3 in person and 3 by telephone	Face to face Individual Telephone	Self-determination Theory Social Cognitive Theory
Gallagher 2012	Weight reduction intervention combining exercise, diet and behaviour change strategies	Waiting list, provided with brochures and information that promote exercise for weight loss	Dietician, clinical psychologist, exercise physiologist, cardiac rehabilitation clinical nurse Consultant Hospital, Australia	16 weeks Exercise: minimum of two x 60 min exercise sessions per week for 16 weeks. Support group: four x 90-min week 1, 2, 4 and 8 (multidisciplinary team)	Face to face Group	
Gray 2013	A weight management programme	Waiting list standard weight loss advice (booklet)	Male community coaches / fieldworkers/health trainers trained to standard protocols Two Premier League football clubs, Scotland	12 weeks Twelve 90 minute, weekly group sessions consisting of classroom-based education + physical activity	Face to face Group	
Greene 2013	A health-oriented online social network	Printed lifestyle guidelines	Unclear Community, USA	24 weeks Private mail. Public postings. View other`s postings and compete in PA	Website Individual Group	
Griffin	Intensive treatment plus a behaviour change intervention	Intensive treatment (3x 10 min with GP + and 3 x 15 min with nurse)	Female trained lifestyle facilitators 34 general practices, England	48 weeks 1 h introductory meeting followed by six 30 min meetings and four brief phone calls	Face to face Individual Telephone	Theory of Planned Behavior Operant learning theory Control theory
Hardcastle 2008	Standard exercise and nutrition information + individual consultations	Standard exercise and nutrition information	Physical activity specialist and registered dietitian trained in MI Local Health Centre, UK	24 weeks 5 x 30 min face-to-face MI counselling sessions over 6-month	Face to face Individual	Self-determination Theory Social Cognitive Theory Transtheoretical model

Additional file 3 Intervention characteristics of 48 PA and diet studies included in review

						of Behavioural Change
Ingelström 2014	CPAP regimen+ behavioral medicine intervention	CPAP regiment+ brief advice to lose weight	Dietitian and physiotherapist with university courses in behavioral medicine University hospital, Sweden	24 weeks 8-10 sessions/6 months, gradually reduced in frequency, and 4 sessions/ 9 months	Face to face Individual	Social Cognitive Theory Self-determination Theory Theory of Self-regulation
Hemmingsson 2008	Added social support on walking	Standard care	Hospital staff Outpatient obesity clinic, University Hospital, Sweden	18 weeks Intervention: standard care 5x 2-h/month meetings + 10 added walking promotion meetings	Face to face Group	Transtheoretical Model of Behavioural Change
Hinderliter 2014	The Dietary Approaches to Stop Hypertension (DASH diet) plus behavioral weight management	Usual care	Nutritionist University Medical center, USA	16 weeks 30-45 min counselling/week. 3 supervised exercise sessions/week	Face to face Group	
Jakicic 2009	Intensive lifestyle weight loss intervention	Diabetes support and education (standard care plus 3education sessions/year)	Unclear Unclear, USA	48 weeks 1–6 month: 3 weekly group sessions and one individual meeting/ month 7–12 months: 2 group meetings + one individual session/month	Face to face Individual Group	
Janus 2012	A primary-care based diabetes prevention programme (Life!)	Usual care by GP	Trained health professionals, a physiotherapist or exercise physiologist and a dietitian co-facilitated Primary health care, Australia	48 weeks 6 group sessions: 1-5 each 2.weeks and 1 session 8 months after the first	Face to face Group	
Kuller 2012	A lifestyle change and weight loss intervention	Health education (6 seminars the first year + more through 36 months	Nutritionists, exercise physiologists, psychologists Community, Pennsylvania, USA	120 weeks 40 visits during 1 first year and a minimum of 12/year 2-3.	Face to face Group	
Leblanc 2012	A Health-At-Every-Size (HAES) intervention	A waiting list control (usual lifestyle habits)	Dietitian, clinical psychologist Community, Canada	16 weeks 14 weekly sessions were scheduled (13 x 3-h evening sessions and 1 intensive-day session of 6 h)	Face to face Group	
Liebreich 2009	The Canadian Diabetes Association's Clinical Practice Guidelines for Physical Activity and Canada's Guide to Physical Activity + The Diabetes NetPLAY intervention	The Canadian Diabetes Association's Clinical Practice Guidelines for Physical Activity and Canada's Guide to Physical Activity	Counsellor with a Bachelor of Science in Physical Education + Masters of Science in Health Promotion Community, Canada	12 weeks Personalized weekly emails, an on-line logbook and message board (forum)	Website Individual	Social Cognitive Theory
Lier 2012	A preoperative counselling program	Treatment as usual: 2x 4 hours educational seminars (preoperative and postoperative)	Psychiatrist, psychologist, physiotherapist Hospital, Norway	12 weeks One preoperative session/week for six weeks, three postoperative sessions 6, 12, 24 months after surgery	Face to face Group	
Logan 2010	Advice to implement a Mediterranean-style diet using behavioural counselling	Conventional dietetic advice for CHD	Research dietitian Hospital, UK	24 weeks A home visit at week 1 (optional), home visits at months 1, 2 and 4	Face- to face Individual Telephone	Social Cognitive Theory Transtheoretical Model of Behavioural Change
Lynch 2014	Health coaching (acceptance and commitment therapy)	Usual-care (educational brochures)	Nurses, psychologists or health promotion practitioners trained in acceptance and commitment therapy Community, Australia	24 weeks 11 sessions/6 months	Face to face Individual Telephone	Acceptance and Commitment theory

Additional file 3 Intervention characteristics of 48 PA and diet studies included in review

Marcus 2013	Culturally adapted, Spanish-language, individually tailored, computer expert system–driven physical activity print-based intervention	A wellness contact control (pamphlets on healthy behaviour)	Researcher Community, USA	48 weeks Print materials by email	Website Individual	Social Cognitive Theory Transtheoretical Model of Behavioural Change
Mascola 2009	Usual medical care plus a brief intervention highlighting the benefits of activity independent of weight-management	Usual care (encouraged to select their own personal health goals and use resources available in their health-care plan and community)	Pre-professional student volunteers with limited clinical experience trained in MI Medical centre, USA	12 weeks 3 in-person consultations followed by up to 4 brief telephone contacts	Face to face Individual Telephone	Intertemporal Bargaining Theory
Miller 2009	A group-based 3-month mindful eating intervention	Diabetes self-management education	Dietitian and social worker with extensive training in mindful meditation Community, USA	12 weeks 8 weekly and 2 biweekly 2½ hour group sessions	Face to face Group	Social Cognitive Theory
Morgan 2011	A weight program	Wait-list control	Male researcher Community, Australia	14 weeks One information session and an free publicly accessible, weight loss website	Face to face Individual Website	Social Cognitive Theory
Nakade 2012	Individual-based counselling	Wait-list control	Registered dietitians and exercise instructors Health doc center, Japan	48 weeks Individual counselling (30 minutes) and group sessions about effective exercise (20 minutes) at baseline and at 1, 3, 6 and 9 months	Face to face Individual Group	Transtheoretical Model of Behavioural Change
Nicklas 2014	Weight loss intervention with a self-regulatory intervention to promote physical activity and decrease sedentary behavior	Weight loss intervention without a self-regulatory intervention	RD and an exercise physiologist Community, USA	20 weeks A controlled diet and 4 days/week of aerobic exercise. In addition, the first 6-weeks: 10-15 min individual session/week. Then biweekly sessions during the 5 months' intervention. During the 5-month follow-up period: brief sessions at 5-week intervals	Face to face Individual	
Nilsen 2011	A low-intensity individual lifestyle intervention by a physician combined with an interdisciplinary, group-based approach	Usual care	Dietician, physiotherapist, ergonomist, nurse, physician using Motivational interviewing techniques University hospital, Norway	16 weeks One day (five hours) /week for six weeks and a new gathering after twelve weeks. An individual 30-minutes consultation completed the intervention one month after the last group meeting.	Face to face Group Individual	
Pakiz 2011	A weight loss intervention	A waiting list	Trained investigators and research staff Community, USA	48 weeks Group sessions weekly for 4 months, and follow-up monthly sessions through 12 months. All intervention subjects also received individualized telephone-based counselling, starting with weekly calls and decreasing infrequency after the first month (every other week for the next 2 months, and once a month thereafter)	Face to face Group Individual Telephone	
Patrick 2011	1-year internet-based weight loss intervention for men	A waiting list	Dietitian, physical activity expert, clinical psychologist Community, USA	48 weeks A web-based assessment of diet and physical activity behaviors and weekly tailored Web modules addressing weight-related behaviors	Website Individual	Social Cognitive Theory
Pekmezi 2009	A Culturally Adapted Physical Activity Intervention for Latinas	A wellness contact control (health information on topics other than physical	Bilingual/bicultural staff Community, USA	24 weeks Monthly mailings of physical activity manuals that were matched to the participants' current level of motivational readiness and individually tailored computer expert-system	Website Individual	Social Cognitive Theory Transtheoretical Model of Behavioural Change

Additional file 3 Intervention characteristics of 48 PA and diet studies included in review

		activity)		feedback reports		
Pettman 2009	A diet and lifestyle modification program for individuals with metabolic syndrome	Written copies of the Australian national guidelines for healthy eating and the Australian National PA guidelines	Study coordinator (with health/ nutrition background) and a peer leader/study coordinator (experienced in adult training and self-management programs) Community, Australia	16 weeks Information and PA sessions for up to 2 h/week	Face to face Group	
Provencher 2009	A Health-At-Every-Size (HAES) intervention	A wait-list	Registered dietitian and a clinical psychologist Community, Canada	20 weeks 14 weekly sessions (13 3-hour evening sessions and one intensive 1-day session lasting 6 hours)	Face to face Group	
Tapper 2009	Mindfulness-based weight loss intervention for women	Continue with their normal diets	Researcher trained in Mindfulness Community, England	15 weeks Three workshops over three consecutive weeks with a fourth follow-up session approximately 3 months later	Face to face Group	
Webber 2010	A motivation-enhanced behavioral weight loss intervention	Standard Intervention	Dietitian trained in MI by the Motivational Interviewing Network of Trainers Community, USA	16 weeks An initial + a four-week two-hour group weight loss session. The website contained weight loss tips, lesson postings, recipes, a message board feature, links to self-help diet, exercise, behavioral modification resources, on-line self-monitoring report	Face to face Group Web based Individual	Self-Determination Theory
Weinstock 2011	Informatics for Diabetes Education and telemedicine intervention and pedometer use on physical activity (PA) and impairment	Usual care	Bilingual educators and diabetes educator Primary care, USA	240 weeks Home visits (videoconference) every 4–6 weeks for 5 years (Telemedicine)	Web based Face to face Individual	
Duda 2014	An autonomy supportive exercise referral program on physical activity, quality of life and well-being indicators	A standard exercise referral program	SDT trained Health and fitness advisor Community, UK	12 weeks One-to-one contact, in person or via telephone, with participants on four occasions	Face to face Individual Telephone	Self-Determination Theory (Basic Needs Theory)
Folta 2009	A community-based program that improve heart health in midlife and older women	A delayed-intervention control group	Cooperative State Research, Education, and Extension educators at the US Department of Agriculture Community, USA	12 weeks 1 hour 2 days per week for 12 weeks	Face to face Group	Social Cognitive Theory

Abbreviations: PA= physical activity.

Additional file 4: Risk of bias in 48 included studies by first author

Type of bias	Adams 2013	Anderson 2014	Annesi 2013	Assunco 2010	Befort 2008	Blomfield 2014	Rejeski 2011	Carr 2008	Carr 2013	Cussler 2008	Dale 2009	De Greef 2011	Eakin 2014	Eriksson 2009	Fortier 2011	Gallanger 2012	Gray 2013	Green 2013	Griffin 2014	Hardcastle 2008	Ingelstrom 2014	Hemmingsson 2008	Hinderliter 2014	Jakicic 2009	Janus 2012	Kuller 2012	Leblanc 2012	Liebreich 2009	Lier 2012
Random sequence generation	L[1]	L	?	L	L	?	L	?	L	?	?	L	L	L	L	L	L	?	L	L	L	?	L	L	L	L	L	L	L
Allocation concealment	?	L	?	L	L	?	L	?	L	?	?	L	L	L	L	L	?	?	L	L	?	?	L	L	L	L	L	L	L
Performance	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H
Blinding of outcome assessment	L	H	H	H	H	H	L	L	L	H	H	H	H L[2]	H	L	H	H	L	L	H	H L	L	H	H	H	H	H	H	H
Attrition	L	L	?	L	H	?	L	H	H	L	L/ H[3]	L	L	L	L	L	L	L	L	H	L	L	L	L	H	L	L	L	L
Reporting	L	L	L	L	L	L	L	L	L	L	H	L	L	L	L	L	L	L	L	L	L	L	L	H	L	L	L	L	L

	Logan 2009	Lynch 2014	Marcus 2013	Mascola 2009	Miller 2009	Morgan 2011	Nakade 2012	Nicklas 2014	Nilsen 2011	Pakiz 2011	Patrick 2011	Pekmezi 2009	Pettman 2009	Provencher 2000	Tapper 2009	Webber 2010	Weinstock 2011	Duda 2014	Folta 2009
Random sequence generation	L	L	L	L	L	L	?	?	L	?	L	L	L	?	L	?	?	L	?
Allocation concealment	L	L	?	L	L	L	?	?	L	?	?	?	?	?	?	?	?	L	L
Performance bias	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	H	L	H
Blinding of outcome assessment	H	H	H	H	H	H	H L	L	H	H	H	H	H	H	H	H	H	L	H L
Attrition bias	L/H	L	L	L	L	L	L	L	L	H	L	L	L	H	L	L	?	L	H
Reporting bias	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	L	H

[1] L = Low risk;? = Unclear risk; H = high risk
[2] H score for diet outcome measure and L score for physical activity outcome measure
[3] L/H means score for short term/long term outcome results

Additional file 5: BCTs unique to the intervention group and not in the control group, coded with The behavior change technique taxonomy (Michie, S., et al. 2013).

BCT	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.2	2.3	2.4	2.7	3.1	3.2	4.1	4.2	4.3	5.1	6.1	6.2	7.1	8.1	8.2	8.7	9.2	11.2	12.5	13.2	13.4
Adams 2013									x													x		x					
Anderson 2014	x	x	x	x	x		x		x	x	x	x	x											x	x		x		x
Annesi 2013										x	x				x	x	x									x			
Assuncao 2010	x		x	x									x						x				x						
Befort 2008								x																	x				x
Blomfield 2014	x		x		x	x	x		x	x	x	x			x			x									x		
Rejeski 2011	x	x	x							x	x	x	x			x			x								x		
Carr 2008	x				x				x				x		x			x	x		x	x	x			x		x	
Carr 2013	x								x	x			x		x			x		x	x						x	x	
Cussler 2008										x	x										x								
Dale 2009	x		x	x						x		x		x	x			x	x			x					x		
De Greef 2011	x	x		x									x		x		x	x							x			x	
Eakin 2014	x	x	x	x	x	x	x		x	x	x	x	x						x		x			x			x		
Eriksson 2009	x	x	x	x								x	x	x					x			x		x	x				
Fortier 2011		x	x	x	x					x			x											x	x	x	x		x
Gallagher 2012	x	x		x						x			x		x			x	x			x	x			x			
Gray 2013	x		x	x				x	x	x	x	x	x		x	x	x					x	x	x		x	x		
Greene 2013										x	x									x	x						x		
Griffin 2014		x																			x						x		
Hardcastle 2008				x	x		x	x					x												x				
Ingelström 2014	x	x	x	x	x			x	x	x					x	x								x					x
Hemmingsson 2008						x								x					x										
Hinderliter 2014	x			x						x			x						x			x					x		
Jakicic 2009	x	x	x	x						x		x	x	x						x			x	x		x	x		
Janus 2012	x		x	x									x		x			x											
Kuller 2012	x	x		x						x			x											x				x	
Leblanc 2012			x										x		x	x		x								x			x
Liebreich 2009	x								x	x			x																
Lier 2012	x	x		x						x			x		x					x		x				x			
Logan 2010	x			x									x											x					
Lynch 2014	x	x		x	x					x			x								x					x	x		x
Marcus 2013	x	x							x	x			x							x	x						x		
Mascola 2009										x														x		x			x
Miller 2009																x	x					x	x			x			
Morgan 2011	x								x	x	x	x	x		x			x						x					
Nakade 2012	x				X				x	x	x		x		x			x	x			x		x					
Nicklas 2014		x			X	x							x										x	x					
Nilsen 2011													x						x			x							
Pakiz 2011	x	x	x		X			x		x			x		x			x				x			x	x			
Patrick 2011	x			x	X	x			x	x			x		x			x					x	x			x		
Pekmezi 2009	x	x							x	x			x		x			x		x							x		

Additional file 5: BCTs unique to the intervention group and not in the control group, coded with The behavior change technique taxonomy (Michie, S., et al. 2013).

Pettman 2009	x	x		x					x	x				x		x			x			x				x	x		
Provencher 2009			x												x		x	x	x			x				x		x	x
Tapper 2009	x		x										x				x									x	x	x	x
Webber 2010					X																				x				
Weinstock 2011							x		x			x			x			x											
Duda 2014		x		x	X		x							x											x			x	
Folta 2009	x									x					x			x	x			x							
Times	30	19	16	21	14	5	6	5	16	28	10	10	30	6	20	7	6	16	14	6	8	15	8	15	9	14	18	8	
BCT	**1.1**	**1.2**	**1.3**	**1.4**	**1.5**	**1.6**	**1.7**	**1.9**	**2.2**	**2.3**	**2.4**	**2.7**	**3.1**	**3.2**	**4.1**	**4.2**	**4.3**	**5.1**	**6.1**	**6.2**	**7.1**	**8.1**	**8.2**	**8.7**	**9.2**	**11.2**	**12.5**	**13.2**	**13.4**

Abbreviations and symbols: BCT: Behaviour change technique identified. Here presented by the difference in BCTs between intervention and control group. Behaviour change techniques are identified using the Behaviour Change Techniques Taxonomy version 1. Results of a systematic review of 48 studies with ≥ 12 weeks' duration for adults (mean age ≥ 40 years and with a mean BMI ≥ 30) published from January 2007 to October 2014.

Additional file 6: Table 4 Results from simple linear meta-regression analysis of short term reports of PA and diet interventions[1]

50 trials at short term									
Covariate	**Classification**	**Trials N**	**Adj. R^2 %**	**Effect size**	**95% CI**	**I^2 (%)**	**b**	**95% CI**	**P value**
None	Overall effect PA + Diet short term	50		0.367	(0.257, 0.477)	71.3			**< 0.001**
Type of behaviour	Physical activity	30		0.358	(0.241, 0.475)	72.2			**< 0.001**
	Diet	20		0.409	(0.196, 0.623)	86.7			**< 0.001**
Risk of bias (High risk or unclear risk)[2]									
	Random sequence		-3.74			71.34	-0.034	(-0.330, 0.264)	0.818
	Allocation concealment		-4.00			71.90	0.075	(-0.190, 0.341)	0.571
	Performance bias (Blinding participants + personnel)		0.51			70.39	0.400	(-0.389,1.189)	0.313
	Detection bias (blinding assessment)		-2.07			71.65	-0.099	(-0.414, 0.215)	0.528
	Attrition bias		-2.58			70.76	-0.068	(-0.367, 0.230)	0.648
	Reporting bias		18.51			68.65	0.670	(0.100, 1.240)	**0.022**
Study characteristics s at short term[3]									
Theory based	yes		-4.07			71.64	0.014	(0.020, 0.135)	0.881
Method based	0=MI + SDT						0.000	reference	
	1=ACT+ CT+ HAES + Mindful or other		-5.53			72.14	0.183	(-0.148, 0.513)	0.272
	2= Unclear						0.179	(0.164, 0.522)	0.299
Single or multiple domain intervention			-3.69			71.37	0.037	(0.233, 0.307)	0.785
Number of BCTs unique in intervention group			23.83			65.29	0.033	(0.008, 0.059)	**0.012**
Total number BCTs intervention + control group			8.85			68.94	0.017	(-0.006, 0.040)	0.136
Type of outcome data	Objective or self-report measure		2.49			70.03	-0.162	(-0.467, 0.142)	0.290
Intervention duration	Weeks		-5.19			71.21	-0.000	(-0.003, 0.003)	0.916
Source of delivery	0= Not health professionals or unclear						0.000	reference	
	1= Profess. trained in behaviour change		6.48			69.46	-0.283	(-0.607, 0.040)	***0.085***
	2= Health profess. other than 1						-0.201	(-0.550, 0.148)	0.252
Format of delivery	0=Individually based only: Face to face or Web						0.000	reference	
	1=Group based or mixed (Individual +group+ web)		-5.27			71.70	0.087	(-0.184, 0.357)	0.522
Treatment setting	0= Community or Workplace						0.000	reference	
	1= Primary care or Hospital		-4.08			71.87	0.053	(-0.217, 0.322	0.696

BCTs at short term[4]	Different BCT	Measure of agreement Kappa	% agreement	Adj. R^2 %	I^2 (%)	b	95% CI	P value
1.1 Goal setting (behaviour)	30	0.602	81.4	49.17	59.29	0.480	(0.257, 0.705)	**< 0.001**
1.2 Problem solving	19	0.532	76.7	-0.71	70.41	0.127	(-0.136, 0.389)	0.338
1.3 Goal setting (outcome)	16	0.705	88.3	2.52	69.88	0.180	(-0.089, 0.449)	0.184
1.4 Action planning	21	0.534	76.8	-3.50	71.72	0.107	(-0.155, 0.369)	0.417
1.5 Review behaviour goals	14	0.239	72.1	-0.65	75.72	0.217	(-0.160, 0.651)	0.313
1.6 Discrepancy between current behaviour and goal	5	0.541	93.1	-2.53	71.14	0.071	(-0.299, 0.441)	0.700
1.7 Review outcome goal(s)	6	0.449	90.7	-3.24	70.92	-0.092	(-0.410, 0.224)	0.559
1.9 Commitment	5	0.452	90.7	-3.15	71.75	0.141	(-0.244, 0.527)	0.466
2.2 Feedback on behaviour	16	0.428	72.1	4.44	71.16	0.219	(-0.040, 0.479)	***0.096***
2.3 Self-monitoring of behaviour	28	0.718	86..0	35.30	62.49	0.398	(0.164, 0.632)	**0.001**
2.4 Self-monitoring of outcome(s) of behaviour	10	0.439	83.7	6.83	68.81	0.192	(-0.116, 0.500)	0.215
2.7 Feedback on outcome of behaviour	10	0.487	83.7	11.99	70.67	0.243	(-0.040, 0.527)	***0.091***
3.1 Social support (unspecified)	30	0.223	62.8	0.93	69.40	0.097	(-0.178, 0.371)	0.483
3.2 Social support (practical)	6	0.534	93.1	-4.22	71.62	-0.019	(-0.443, 0.407)	0.943
4.1 Instruction how to perform the behaviour	20	0.348	67.5	-2.70	71.91	0.168	(-0.095, 0.432)	0.205
4.2 Information on antecedent	7	0.292	83.8	-4.02	71.87	-0.005	(-0.365, 0.355)	0.978
4.3 Re-attribution	6	0.325	86.1	-2.75	71.81	-0.131	(-0.531, 0.269)	0.514
5.1 Information about health consequences	16	0.579	79.1	-3.64	71.83	0.064	(-0.215, 0.342)	0.648
6.1 Demonstration of the behaviour	14	0.546	79.1	11.93	68.64	0.244	(-0.035, 0.523)	***0.085***
6.2 Social comparison	6	0.422	86.1	-1.41	71.26	0.191	(-0.351, 0.733)	0.548
7.1 Prompts/cues	8	0.366	83.7	-0.31	70.71	0.153	(-0.186, 0.492)	0.368
8.1 Behavioural practice /Rehearsal	15	0.514	79.0	3.80	70.36	0.193	(-0.109, 0.495)	0.205
8.2 Behaviour substitution	8	0.271	83.8	-2.35	71.79	-0.130	(-0.480, 0.220)	0.485
8.7 Graded tasks	15	0.475	79.1	2.95	69.79	0.210	(-0.062, 0.482)	0.127
9.2 Pros and cons	9	0.758	93.1	4.77	70.82	-0.252	(-0.542, 0.038)	***0.087***
11.2 Reduce negative emotions	14	0.606	88.3	7.08	71.01	-0.237	(-0.523, 0.492)	0.102
12.5 Adding objects to the environment	18	0.473	74.4	10.67	67.33	0.194	(-0.061, 0.450)	0.133
13.2 Framing/ reframing	8	0.372	83.7	-2.97	71.90	0.115	(-0.266, 0.496)	0.546
13.4 Valued self-identity	9	0.271	83.8	-1.68	71.85	-0.076	(-0.383, 0.230)	0.617

Abbreviations and symbols: BCT: behaviour change technique; PA: physical activity; b: estimated meta-regression coefficient; CI: confidence interval; Adj. R^2: adjusted proportion of between study variance explained by predictors. [1]) Pooled estimates of physical activity and diet intervention's outcome reports from 48 studies. Simple linear meta-regression of pooled estimates of 30 physical activity and 20 diet intervention's outcome reports. Short term represents post-intervention reports ≤6 months. [2]) High and unclear risk of reporting bias versus low risk. [3]) MI = Motivational Interviewing; SDT = Self-Determination theory based interventions; ACT = Acceptance and commitment therapy; CT = Cognitive therapy; HAES = Health-at-every-size approach; Mindful= Mindful based intervention program. [4]) The difference of BCTs between intervention and control group contains this BCT, compared to studies not having this difference.

Additional file 7: Table 5 Results from simple linear meta-regression analysis of long term reports of PA and diet interventions[1]

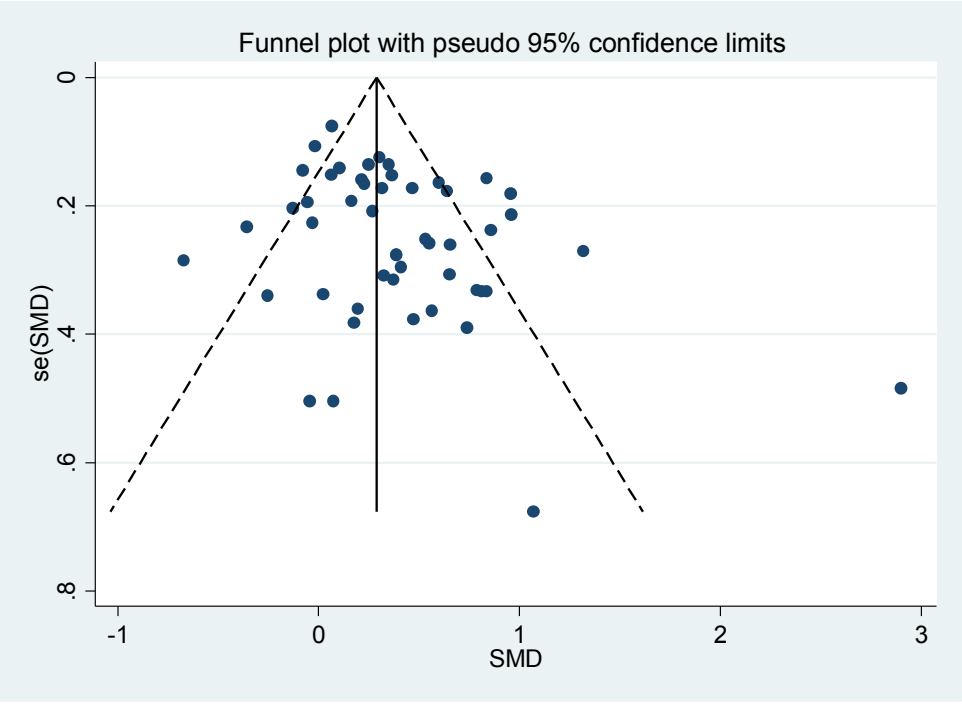
32 trials at long term									
Covariate	**Classification**	**Trials N**	**Adj. R^2 %**	**Effect size**	**95% CI**	**I^2 (%)**	**b**	**95% CI**	**P value**
None	Overall effect PA + Diet long term	32		0.240	(0.150, 0.330)	59.4			**< 0.001**
Type of behaviour	Physical activity	17		0.254	(0.126, 0.383)	79.6			**<0.001**
	Diet	15		0.191	(0.072, 0.310)	53.8			**<0.001**
Risk of bias (High risk or unclear risk)									
	Random sequence		1.85			57.19	-0.129	(-0.359, 0.101)	0.261
	Allocation concealment		2.23			55.93	-0.105	(-0.305, 0.095)	0.293
	Performance bias (Blinding part. + person)								
	Detection bias (blinding assessment)		-9.42			59.75	-0.048	(-0.265, 0.170)	0.657
	Attrition bias		6.02			56.53	-0.136	(-0.368, 0.097)	0.242
	Reporting bias		26.77			39.14	0.235	(-0.054, 0.524)	0.107
Study characteristics at long term[2]									
Theory based	Yes		0.47			52.42	-0.039	(-0.218, 0.140)	0.661
Method based	0=MI + SDT						0.000	reference	
	1=ACT+ CT+ HAES + Mindful or other		57.54			31.15	-0.303	(-0.500, -0.105)	**0.004**
	2= Unclear						-0.199	(-0.372, -0.026)	**0.026**
Single or multiple domain intervention			4.01			52.77	-0.077	(-0.253, 0.099)	0.380
Number of BCTs unique to the intervention group			54.23			28.79	0.028	(0.012, 0.044)	**0.001**
Total number BCT in intervention and control group			61.26			23.29	0.030	(0.014, 0.046)	**0.001**
Type of outcome data	1= Objective outcome		-9.69			59.56	-0.046	(-0.253, 0.161)	0.652
	2= Subjective outcome						0.000	reference	
Intervention duration	Weeks		-7.46			60.65	0.001	(-0.001, 0.003)	0.272
Source of delivery	0= Not health professionals or unclear						0.000	reference	
	1= Profess. trained in behaviour change		5.91			44.99	-0.128	(-0.395, 0.138)	0.333
	2= Health profess. other than 1					44.99	-0.080	(-0.349, 0.188)	0.545
Treatment setting	0= Community or Workplace								
	1= Primary care or Hospital		-7.07			59.36	0.020	(-0.170, 0.210)	0.828
Format of delivery	0=Individually based only: Face to face or Web						0.000	reference	
	1=Group based or mixed (Individual +group+ web)		6.00			25	-0.096	(-0.322,0.131)	0.396

BCTs at long term[3]	Different BCT	Adj. R^2 %	I^2 (%)	b	95% CI	P value
1.1 Goal setting (behaviour)	30	38.51	43.56	0.228	(0.056, 0.400)	**0.011**
1.2 Problem solving	19	25.06	47.16	0.161	(-0.005, 0.327)	***0.057***
1.3 Goal setting (outcome)	16	53.15	30.78	0. 256	(0.095, 0.416)	**0.003**
1.4 Action planning	21	15.18	50.41	0.125	(-0.049, 0.299)	0.152
1.5 Review behaviour goals	14	19.80	62.96	-0.319	(-0.678, 0.040)	***0.078***
1.6 Discrepancy between current behaviour and goal	5	-6.53	60.70	0.114	(-0.133, 0.360)	0.354
1.7 Review outcome goal(s)	6	-6.77	60.64	0.115	(-0.098, 0.327)	0.279
1.9 Commitment	5	9.58	57.18	-0.268	(-0.639, 0.107)	0.156
2.2 Feedback on behaviour	16	-9.32	60.37	0.131	(-0.056, 0.318)	0.163
2.3 Self-monitoring of behaviour	28	30.81	47.09	0.184	(0.009, 0.3609)	**0.040**
2.4 Self-monitoring of outcome(s) of behaviour	10	-3.50	60.72	0.117	(-0.074, 0.307)	0.220
2.7 Feedback on outcome of behaviour	10	43.78	35.35	0.249	(0.085, 0.412)	**0.004**
3.1 Social support (unspecified)	30	21.59	50.86	0.192	(-0.011, 0.394)	***0.063***
3.2 Social support (practical)	6	10.09	43.75	0.137	(-0.132, 0.405)	0.307
4.1 Instruction on how to perform the behaviour	20	2.24	55.37	-0.087	(-0.274, 0.100)	0.350
4.2 Information on antecedent	7	-3.06	60.47	0.215	(-0.258, 0.689)	0.361
4.3 Re-attribution	6	-2.87	60.28	-0.129	(-0.732, 0.475)	0.666
5.1 Information about health consequences	16	-3.16	57.10	-0.036	(-0.230, 0.157)	0.705
6.1 Demonstration of the behaviour	14	-8.72	60.23	0.070	(-0.120, 0.259)	0.459
6.2 Social comparison	6	7.34	43.24	0.098	(-0.205, 0.402)	0.513
7.1 Prompts/cues	8	-3.79	57.57	-0.031	(-0.236, 0.173)	0.755
8.1 Behavioural practice /rehearsal	15	5.53	55.82	-0.121	(-0.317, 0.074)	0.214
8.2 Behaviour substitution	8	3.33	48.03	0.096	(-0.140, 0.332)	0.412
8.7 Graded tasks	15	37.10	41.31	0.203	(0.043, 0.363)	**0.014**
9.2 Pros and cons	9	-5.45	59.70	-0.030	(-0.276, 0.217)	0.810
11.2 Reduce negative emotions	14	-2.88	49.22	0.035	(-0.195, 0.265)	0.759
12.5 Adding objects to the environment	18	12.72	49.94	0.182	(0.010, 0.354)	**0.039**
13.2 Framing/ reframing	8	-5.58	60.71	0.050	(-0.253, 0.353)	0.738
13.4 Valued self-identity	9	-5.86	60.71	0.092	(-0.151, 0.334)	0.447

Abbreviations and symbols: BCT: behaviour change technique; PA: physical activity; ß: estimated meta-regression coefficient; CI: confidence interval; Adj. R^2: adjusted proportion of between study variance explained by predictors. [1]) Simple linear meta-regression of pooled estimates of 17 physical activity and 15 diet intervention's outcome reports from 48 studies. Long term outcome reports represented last follow-up, ≥12 months. [2]) High and unclear risk of reporting bias versus low risk; MI = Motivational Interviewing; SDT = Self-Determination theory based interventions; ACT = Acceptance and commitment therapy; CT = Cognitive therapy; HAES = Health-at-every-size approach; Mindful= Mindful based intervention program. [3]) The difference of BCTs between intervention and control group contains this BCT, compared to studies not having this difference.

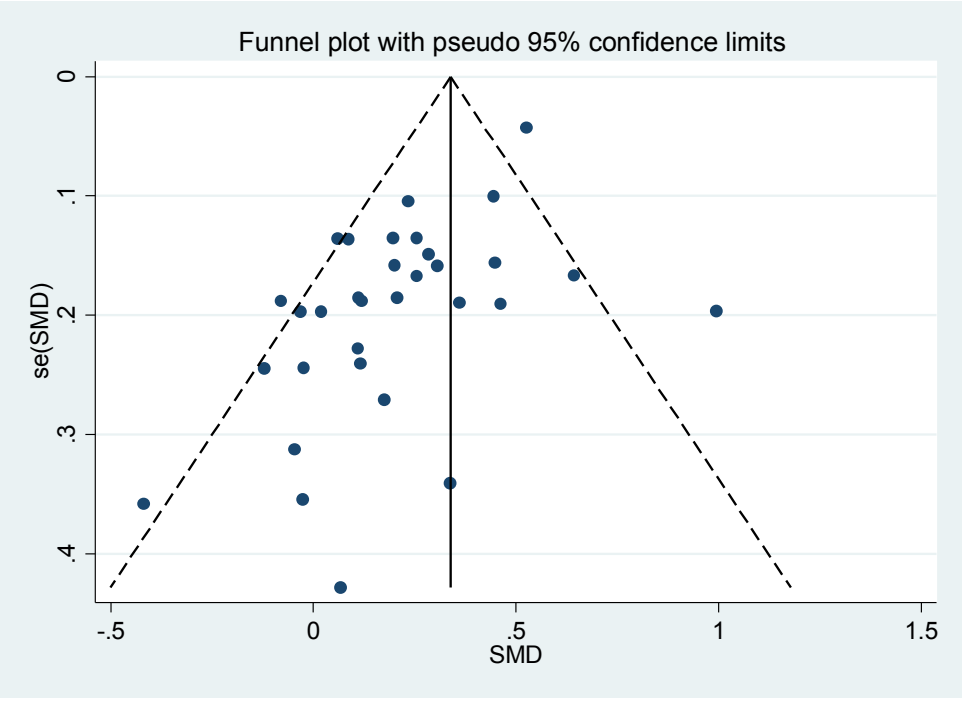
Additional file 8:

Figure 1 Funnel plot of 50 outcome reports at short term (≤ 6 months) from diet and physical activity interventions for overweight and obese adults from January 2007 to October 2014



Additional file 9:

Figure 1 Funnel plot of 32 outcome reports at long term (≥ 12 months) from diet and physical activity interventions for overweight and obese adults from January 2007 to October 2014



Paper II

II

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STUDY PROTOCOL Open Access

The Norwegian Healthy Life Study: protocol for a pragmatic RCT with longitudinal follow-up on physical activity and diet for adults

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Abstract

Background: The Norwegian Directorate of Health recommends that Healthy Life Centres (HLCs) be established in primary health care to support behaviour change and reduce the risk of non-communicable diseases. The aim of the present study protocol is to present the rationale, design and methods of a combined pragmatic randomized controlled trial (RCT) and longitudinal cohort study of the effects of attending HLCs concerning physical activity, sedentary behaviour and diet and to explore how psychological well-being and motivational factors may mediate short— and long-term effects.

Methods: The present study will combine a 6-month RCT with a longitudinal cohort study (24 months from baseline) conducted at six HLCs from June 2014 to Sept 2017. Participants are randomized to behavioural change interventions or a 6-month waiting list control group.

Discussion: A randomized trial of interventions in HLCs has the potential to influence the development of policy and practice for behaviour change interventions and patient education programmes in Norway. We discuss some of the important preconditions for obtaining valid results from a complex intervention and outline some of the characteristics of ecological approaches in health care research that can enable a pragmatic intervention study.

Trial registration: The study was retrospectively registered on September 19, 2014 and is available online at ClinicalTrials.gov (ID: NCT02247219).

Keywords: Randomized control trial, Health behaviour, Physical activity, Diet, Adults

Background

Lifestyle risk factors are recognized as a leading contributor to morbidity and mortality in Europe due to the development of non-communicable diseases (NCDs). There is by now solid evidence for the causal link between regular physical activity (PA), healthy dietary habits and good health [1]. The WHO's Global Action Plan urges national governments to develop NCD targets and plan how the health care system should respond to these targets [1]. As part of the national NCD strategy [2], the Norwegian Directorate of Health recommends that Healthy Life Centres (HLCs) be established in primary health care [3]. The target group is persons of all ages with a high risk of contracting a disease, or who are already living with a disease and need help to change their health behaviour and manage their condition.

HLCs offer individual and group-based behavioural change intervention programmes focusing mainly on the promotion of healthy dietary and physical activity habits as well as smoking cessation. At a system level, HLCs aim to function as a resource, knowledge and contact centre for behaviour change, health promotion and disease prevention in the municipalities. By targeting

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NCD risk in vulnerable groups, HLCs are one of the national strategies and efforts aiming to reduce social health inequalities [4]. By the end of 2014, 57% of Norwegian municipalities provided HLC activities, and the number of established HLCs doubled during the period 2011–2014 [5].

However, the scientific evidence for health promotion effectiveness is not convincing in a primary care setting similar to HLCs [6], and the pathways and mediators linking unhealthy behaviour to deteriorated health are not well understood [7]. A review study evaluating the effectiveness of interventions comparable to the Norwegian HLC model reported conflicting results, noting that the included studies were hampered by methodological insufficiencies [8].

Behavioural change intervention programmes at HLCs are complex interventions, with a number of interacting components and outcomes. In complex interventions based on real-life settings, randomized controlled trials (RCTs) may have limited impact on practice and policy, since the impact of interacting contextual factors differs by location [9]. Lewis et al. suggested to design theory-based interventions and include theory-derived mediating variables to identify effective interventions and techniques [10]. The UK Medical Research Council (MRC) has developed guidance to design and evaluate complex interventions [9]. A realist evaluation approach may enable complex interventions to address questions about what works, for whom and under what circumstances [11], and take into account that generation of knowledge may come from practitioners involved in a study as well as from the researchers [12].

The Norwegian Directorate of Health recommends that HLCs adopt an approach based on salutogenesis [13], and use motivational interviewing (MI) as a counselling approach [14]. The trans-theoretical model of change [15], used in addition to MI, provides counsellors with a conceptual model to explain why some people change while others do not [16]. Self-determination theory (SDT) suggests that counsellors may enhance behaviour change and maintenance of new habits by positively influencing the quality of clients' motivation by supporting the three basic psychological needs, namely autonomy, competence and relatedness [17]. Need-supportive interventions and a more autonomous regulation of behaviour have been shown to predict success in many domains, including long-term weight control [18], tobacco dependence [19], predicting psychological well-being [20] and exercise [21]. Moreover, successful self-regulation in physical activity has been shown to spread and affect other behaviour domains, such as the regulation of eating [22]. Autonomous regulation of eating has been associated with healthier eating, being concerned with what one eats (the quality of food), a predictable reduction in food calories, eating more fruits and vegetables and food planning [23]. Body dissatisfaction, obesity and dysfunctional eating are often associated with a controlled regulation of eating behaviour [24]. Even though MI has been developed as a clinical tool and SDT is an empirically based theory, there are similarities and conceptual overlap between them [25]. MI supports the participants' need for autonomy and relatedness by allowing them freedom to explore reasons for and against change (autonomy) in a non-judgemental context (relatedness) [25].

The HLC model is still in development, and is expected to expand and include patient education and self-management programmes targeting the most prevalent NCDs [3]. Consequently, there is a lack of studies evaluating the effect of HLC programmes. Results from a prospective intervention study with a 12-month follow-up indicated that participation in a group-based prescribed PA programme for 3 months significantly improved physical fitness and health-related quality of life (HRQoL) post intervention and at follow-up [26]. However, the generalizability of these findings is affected by high drop-out rates and should therefore be interpreted with caution. A qualitative study by Følling et al. [27] indicated that emotional distress among Norwegian HLC participants may hamper behaviour change; doubts were raised about whether HLC interventions are sufficient to provide maintenance of change due to previous negative life experiences, shame and low self-efficacy among the participants. Thus, there is a need to evaluate the effects of the Norwegian HLC model.

In the process of developing the intervention study described in this protocol paper, we have previously reported a focus group study exploring stakeholders' expectations at seven different HLCs in small and large municipalities [28]. We explored the local adaptation of the HLC model and the contextual diversity of behavioural change programmes and competence available at different sites. Based on this understanding, we designed an RCT based on common intervention components, methods and theoretical input at the HLCs included in the study.

Aims

The aims of the present study were to evaluate (1) the short— and long-term effects of behavioural change intervention in Norwegian HLCs on physical activity, self-perceived health and well-being, self-reported diet and eating behaviour, tobacco use, and sleep and body concern, (2) the factors that mediate these effects and (3) the possible adverse effects of the intervention.

Methods/design

The Norwegian Healthy Life Study is a 6-month RCT with a longitudinal follow-up (24 months after inclusion)

to assess the effectiveness of behaviour change interventions in HLCs for adults, with the underlying purpose being to develop a pragmatic intervention informed by an ecological model of health [29]. Based on theoretical assumptions and previous research, we hypothesize that (1) an increase in PA and a healthier diet will be observed in the intervention group, compared with the waiting list control group, (2) participants who experience the health personnel as supportive of autonomy will report more autonomous reasons, less nudging and less psychological defiance of behaviour change during short— and long-term follow-up and (3) beneficial changes in motivation and well-being will ameliorate socio-economic differences in maintenance of behaviour change at follow-up.

The study will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement [30] and the Template for Intervention Description and Replication (TIDieR) [31]. The protocol is available online at ClinicalTrials.gov (ID: NCT02247219).

Setting

The members of the research group invited 12 municipalities to participate in the research programme. Four declined (one due to other research commitments at the HLC), leaving a sample of eight municipalities (with 6,000–270,000 inhabitants) with a total number of 630,000 inhabitants living in rural and urban areas on the west and south coast of Norway. The study is designed as a pragmatic RCT, based on an ecological understanding that behaviour change interventions must take into account the participants' personal aspects (microsystem), their close supporters (mesosystem), the everyday environmental factors (exosystem) and finally structures and regulations on a systems level (macrosystem) [29].

Throughout the development of the intervention, we studied the HLC activities in different settings, and arranged seminars with involved counsellors, leaders and representatives of patient organizations [28]. Themes at these seminars included discussions of MI counselling, relevant theory, experiences in face-to-face counselling in a HLC setting, social determinants of health, aspects related to behaviour change among immigrants, medical ethics, dietary counselling and how to improve PA. In line with current recommendations for pragmatic RCTs, the local implementers were treated as co-learners in the development of the intervention model. The meetings with implementation staff built on local experiences and emphasized existing competence and skills. In meeting with the different local professional groups, the research group conveyed interest in individual and organizational challenges and emphasized support and respect for local competence and the quality of services.

Inclusion criteria

Patients had to be ≥18 years old and able to participate in a group intervention held in the Norwegian language.

Exclusion criteria

These included having disabling mental illness, mental retardation or only attending a smoking cessation intervention and not a PA and/or diet intervention.

Recruitment

The local HLCs invited 351 persons (59% women) to participate in the study. Participants were referred by their general practitioner (GP), other health professionals or initiated attendance themselves. In the period June 2014–September 2015, 118 participants (34% of those invited; 77% women) were recruited. The main reason for refusing participation was the possibility of having to wait 6 months for the intervention if randomized to the waiting list control group.

Interventions

The intervention group receives interventions according to the Norwegian Healthy Life model, as defined by the Norwegian Directorate of Health [3]. The model consists of (1) an individual counselling session based on referral from a GP, other health care providers or self-referral, (2) group-based behavioural change interventions for 12 weeks and (3) an individual counselling session by the end of the intervention (Fig. 1). The counselling sessions are based on MI.

The organization of the HLCs and the content of the intervention vary between the municipalities according to local resources and competence. Depending on availability, professionals involved may be physiotherapists, nutritionists, occupational therapists, trained lifestyle counsellors and PA instructors with a bachelor's or master's degree in nutrition and/or sports science and health promotion; or nurses trained in public health or psychiatry. During the first individual session of 30–60 minutes, the counsellor elicits and acknowledges the participant's perspective on health, offers information about health consequences, and outlines the HLC's PA, diet and/or stop smoking intervention support. Strategies are discussed to overcome barriers and facilitate change and set realistic targets. Graded goals for behaviour change are negotiated and confirmed in a written action plan.

The participants are encouraged to monitor their behaviour, e.g. in a log-book, and use web-based applications for support, e.g. the national stop smoking app. Group-based PA consisting of elements from aerobic training (e.g. Nordic walking), light strength training, stretching and games is encouraged twice a week. A course promoting healthy eating (10 hours) includes

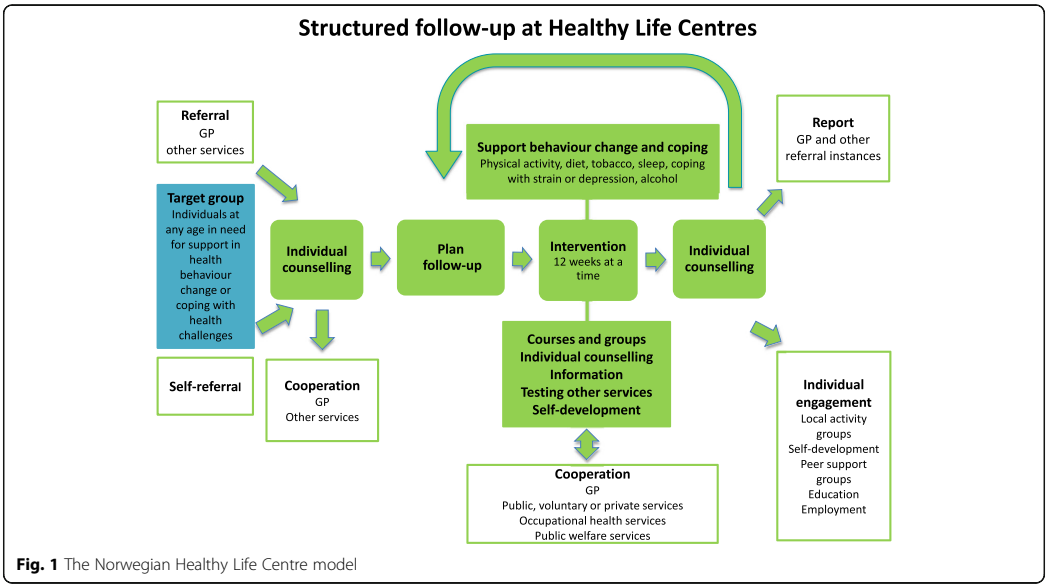

Fig. 1 The Norwegian Healthy Life Centre model

information about meal composition, beverages, meal size, and demonstration and practice, e g. how to read food labels and prepare healthy food and beverages. If intending to stop smoking, participants are offered group-based smoking cessation counselling. The group-based interventions provide opportunities for social support and encouragement among participants in the same situation.

After 12 weeks of participation in group-based activities, there is a second individual counselling session of 30–60 minutes to review behaviour goals and the outcomes of behaviour change, e.g. weight loss and fitness, with the counsellor offering feedback on results. If there is a need and motivation for further interventions, the participants may extend their participation period several times, up to one year. Some HLCs ask for a small fee (ca. €50) for attending the HLC programme to increase the participant's commitment to the programme. After the intervention (at 6 months) and at the 24-month follow-up, the participants are asked about the types of intervention they attended and how long their participation lasted.

Control group

The control group receives the same intervention after a waiting period of at least 6 months. The control group was told to live as normal, and no restriction was given with respect to behaviour change. The majority of the HLCs included new participants according to local capacity, with the consequence that both intervention and control group participants may have to wait for a while.

Randomization and allocation

Participants are randomly assigned by a simple method using a random number list and an approach that ensures equal distribution in the intervention and control groups. A project co-ordinator, working outside the HLC premises, assigns participants to either the intervention group or the waiting list by drawing cards from numbered sealed 2envelopes after the inclusion visit and registration of inclusion data, thereby ensuring concealment of the sequence to those enrolling the patients and of the identity and patient characteristics to the researcher. A block randomization is performed with randomization stratified by trial site in blocks of 20 to avoid uneven distribution of participants at any of the HLCs.

Blinding

It is not possible to blind either the participants or the staff performing the interventions to group allocation. Blinding of assessment is aimed at by means of objective PA and sedentary time measurements (described below) and by online self-reported data collection (described below).

Data collection

Self-reported data are collected by an online system for survey management, SurveyXact™ (Rambøll Management

Consulting, Oslo, Norway). The counsellors help the participants to access the online survey, and are then left alone in a separate room until the survey is completed. The survey was tested on four participants at two HLCs, who found the questions understandable and possible to complete in 30–45 minutes. Data are collected at the local HLC prior to randomization (baseline), after 6 months (post intervention) and 24 months after baseline from the intervention group participants. Waiting list controls perform registration of data at inclusion, after 6 months on the waiting list, at 12 months (post intervention) and at the 24-month follow-up. A SPIRIT flow diagram illustrates the data collection in the intervention group and control group [32] (Tables 1 and 2).

Biomedical and socio-demographic data

At inclusion, the counsellors at the HLCs measure the participant's weight, height and waist circumference (light clothing, no shoes), and give each participant a unique number in the survey. Waist circumference is measured at the level of the umbilicus. The questionnaire includes questions about socio-demographic data, the reasons for attending the HLCs, and total time of participation and types of intervention received at follow-up.

Primary outcomes

Primary outcome measures will be the objective measurement of moderate-to-vigorous physical activity (MVPA).

Physical activity

Participant's PA will be recorded (1) objectively by a PA monitor (SenseWear™ Armband Mini, BodyMedia Inc., Pittsburgh, PA, USA) and (2) by two survey questions: "In general, for how long are you physically active each day?"; and "How hard do you exercise?". These questions have been previously validated in comparison with biological markers in Norwegian adults [33]. Study participants are instructed to wear the monitor on the upper left arm (the triceps muscle), according to the manufacturer's instructions, for 24 hours a day for 7 consecutive days, except for water-based activities.

The monitor is reliable, valid and suitable for measuring daily living PA in normal and overweight adults [34, 35]. Data are downloaded with the manufacturer's software (SenseWear™ Professional Research Software Version 7.1, BodyMedia Inc). The analysis includes only data from participants with ≥4 valid days of measurements. Valid data should cover at least 19.2 hours during that given day, i.e. 80% of a 24-hour sampling period. PA intensity is defined

Table 1 The intervention group

Intervention group	Study period			
	Enrolment	Allocation		
	T_0		T_2 6 months	T_4 24 months
Enrolment				
Eligibility screen	x			
Informed consent	x			
Allocation		x		
Intervention				
Assessments				
Biomedical data	x		x	x
Socio-demographic data	x			
PA monitor	x		x	x
PA questionnaire	x		x	x
Self-perceived health and well-being	x		x	x
Diet and eating behaviour	x		x	x
Tobacco use	x		x	x
Sleep	x		x	x
Body concern	x		x	x
Social support	x		x	x
Defiance	x		x	
Regulation of motivation	x		x	x
Perceived autonomy support			x	
Self-efficacy for PA	x		x	

Table 2 The control group

Control group	Study period				
	Enrolment	Allocation	Post allocation		
	T_0		T_1 6 months	T_3 12 months	T_4 24 months
Enrolment					
Eligibility screen	x				
Informed consent	x				
Allocation		x			
Intervention					
Assessments					
Bio-medical data	x		x	x	x
Socio-demographic data	x				
PA monitor	x		x	x	x
PA questionnaire	x		x	x	
Self-perceived health and well-being	x		x	x	x
Diet and eating behaviour	x		x	x	x
Tobacco use	x		x	x	x
Sleep	x		x	x	x
Body concern	x		x	x	x
Social support	x		x	x	x
Defiance	x		x	x	
Regulation of motivation	x		x	x	x
Perceived autonomy support				x	
Self-efficacy for PA	x		x	x	

using metabolic equivalents of task (METs) as minutes spent sedentary (≤1.0–1.4 METs), light PA (1.5–2.9 METs) and MVPA (≥3 METs). Thus, sedentary time, steps per day and light PA are used as secondary outcomes.

Secondary outcomes

Secondary outcome variables will also include self-perceived health and well-being, self-reported diet and eating behaviour, tobacco use, sleep and body concern.

Self-perceived health and well-being

Self-rated health is measured by the single item question "How is your overall health at the moment?" previously used in a Norwegian study [36]. The four response categories are "Very good", "Good", "Not so good" and "Poor".

Information on quality of life is assessed using Cantril's ladder [37]. The Impact of Weight on Quality of Life-Lite Questionnaire (IWQOL-Lite) is a validated, self-report measure of obesity-specific quality of life [38]. In this study, we use nine of the 31 items that cover quality of life in relation to the domains physical function and self-esteem.

The single-item self-esteem scale (SISE) is used to assess global self-esteem [39]. The IWQOL-Lite also contains a self-esteem construct with four items [38]. The scales have proved to have strong construct validity when applied to adult populations.

Vitality is assessed by the Subjective Vitality Scale, a measure of the state of feeling alive and alert, and of having energy available to the self [40]. Vitality is considered an aspect of eudemonic well-being [41].

In studies linking childhood experience of parental acceptance and rejection to adult behavioural and emotional adjustment, the phenomenological perspective, i.e. the remembrance and the personal evaluation of the relation with caregivers, is the most prominent [42]. We have included a single self-assessment item of the quality of childhood, similar to a question that proved to be associated with multi-morbidity and allostatic load in a recent Norwegian study [43].

Diet and eating behaviour

The survey includes questions on meal pattern, and habitual diet and beverage consumption. The questions assessing meal frequency, meal composition and use of beverages were previously used in Norwegian health

surveys [44]. Meal frequency is assessed by questions such as "How often do you have breakfast each week?" with the same asked for lunch, dinner and supper. Response alternatives range from never or seldom to seven days a week.

Beverage consumption is assessed by questions such as "How often do you drink water, regular soft drinks, diet soft drinks, lemonade and fruit juice?"; consumption of food items is assessed by questions such as "How often do you eat candy, salty snacks, cakes/cookies/pastries, fast food, nuts, high-fat and low-fat dairy products, fish, red and white meat and oils?". The frequency of food and beverage consumption is assessed by ticking response alternatives coded per week or per day.

We emphasize diet items pertaining to the Mediterranean diet because this diet has documentation on hard endpoints in secondary as well as in primary preventive studies [45, 46]. The Mediterranean diet index includes 11 main components of the Mediterranean diet (unrefined cereals, fruits, vegetables, potatoes, legumes, olive oil, fish, red meat, poultry, full-fat dairy products and alcohol) [47].

The Three-Factor Eating Questionnaire-R18 is an 18-item questionnaire previously used in an intervention study targeting obese subjects in Norway [48], and is considered a robust scale to measure cognitive restraint, uncontrolled eating and emotional eating.

Tobacco

Use of tobacco will be assessed by the single question "Do you smoke or use snuff?" with "Yes, I smoke daily", "Yes, I smoke but not daily", "Yes, I use snuff daily", "Yes, I snuff but not daily" or "No" as alternative responses.

Sleep

A structured log-book with five items assesses sleep patterns [49]. The participants are instructed to write a report first thing on seven consecutive mornings.

Body concern

We use three questions pertaining to body concern validated in the Health Behaviour in School-aged Children study [50] and the Body Attitude Test with seven items measuring lack of familiarity with one's body [51].

Mediating variables

Mediating variables include social support in general, social support for PA, defiance, regulation of motivation, perceived autonomy support and self-efficacy for PA.

Social support in general

The Oslo-3 Social Support Scale (OSS-3) with three questions, previously used in Norwegian context, assesses social support [52, 53]. A mean score is estimated from a minimum of two questions.

Social support for PA

Social support for PA from friends and family is measured using a scale developed by Sallis et al. [54] previously used in Norwegian surveys [55].

Defiance

Psychological defiance pertains to the tendency of oppositional rejection of advice and opinions from authority persons. Four items derived from research on parenting styles with a high inter-item reliability were adapted and slightly changed in wording to fit our context [56, 57].

Regulation of motivation

The Treatment Self-Regulation Questionnaire (TSRQ) (15 items) assesses the degree to which a person's motivation for a particular behaviour is relatively autonomous or self-determined. In this case, the particular behaviour is joining a behaviour change programme and following its guidelines for exercise and a healthy diet, or continuing to follow the guidelines after the programme has ended. The questionnaire was validated by Levesque et al. [58] and has been used in various studies, including in Norway [59]. The scale identifies differences in types of regulation (subscales), amotivation (lacking any intention to engage in behaviour) (3 items), and controlled (6 items) and autonomous motivation for behaviour change (6 items). Responses are rated on a 7-point Likert scale ranging from "strongly disagree" to "strongly agree". Examples of items included in the different subscales are "I really don't think about it", "Because I want others to see that I can do it", and "Because I feel that I want to take responsibility for my own health". The subscales are averaged and can be used separately.

Perceived autonomy support

The 6-item version of the Health Care Climate Questionnaire (HCCQ) measures the degree to which patients experience their health care providers to be autonomy supportive versus controlling in counselling with respect to behavioural change [19]. Responses are rated on a 7-point Likert scale ranging from "strongly disagree" to "strongly agree". Higher scores represent greater perceived support for autonomy by health care professionals after an intervention. This instrument has been extensively validated and used in various studies targeting obesity, smoking cessation, diet improvement and regular exercise [60, 61], also in a Norwegian setting [62]. The HCCQ was reduced from six to four items in the present study after tests on a dataset of patients with coronary artery disease showing no loss of inter-item

reliability (Cronbach's alpha = 0.89). Due to ceiling effects and low variability in a former study [63], the midpoint on the scale was moved in the opposite direction of the ceiling, yielding acceptable variability in each of the four items and with absolute values of skewness <1.0.

Self-efficacy for PA

Self-efficacy for PA is assessed by a questionnaire previously used in Norwegian studies [44, 64], representing eight psychological and five practical barriers. Participants are asked to indicate on a 7-point Likert scale (ranging from "not at all confident" to "extremely confident") to what extent they were confident in their ability to perform planned PA in the face of potential barriers.

Sample size and statistical power

Power calculations showed that 51 adults are required in each group to obtain 80% statistical power with a 5% significance level, and to detect a between-group difference in MVPA of 10 (standard deviation 20) min/day. To account for drop-out, 118 persons are included, 57 in the intervention group and 61 in the control group.

Statistical analysis

Data are presented by descriptive statistics. Statistical analysis is conducted by SPSS (Statistical Package for the Social Sciences) or equivalent. The study provides standard means and deviation of each variable for the participants in the intervention and control groups. The waiting list design controls for cross-over and interaction effects. We also perform intention-to-treat analyses with conservative estimates of missing data. A baseline comparability analysis across the two intervention groups is also carried out, with results expressed by means and ± standard deviation. To compare means, analysis of variance or t tests are performed; Mann–Whitney U tests are used to compare variables with non-normal distribution. Intervention effects are evaluated performing general linear modelling. Mediator and moderator analyses will apply regression analyses.

Discussion

The MRC guidance on developing and evaluating complex interventions puts emphasis on theoretical understanding of how the intervention causes change, identification of implementation problems, consideration of sample size based on variability of individual-level outcomes due to higher-level processes, a range of measures instead of a single outcome, and a specified degree of adaptations to local context instead of strict standardization [9]. In the present study, we have selected multiple measures informed by theories of behavioural change with SDT as a point of departure in an ecological approach [29]. SDT supports an ecological understanding of behaviour where no priority is placed on the individual, group or environment. Relatedness is built when the client feels understood, cared for and valued by significant others (family, health personnel, community). This also emphasizes how the social context may support or thwart optimal motivation [17].

Context is important in research on health behaviour change, and knowledge translation, practice implementation and health improvement are dependent on local factors. Many intervention and evaluation designs seek to eliminate contextual confounders. In opposition to this view, we maintain that contextual factors represent the normal conditions into which interventions must be integrated if they are to be workable in practice [65]. In the present study, a strategic sample of municipalities representing diverse contexts participates, with the aim of increasing the external validity of the study.

Strengths and limitations

A pragmatic approach taking into account local resources and preferences should enhance the external validity of our findings. On the other hand, the intervention is not optimally standardized. However, the call for standardizing complex interventions is a "double-edged sword" often leading to a lack of local ownership and low quality of the interventions and even sapping the effectiveness of well-designed studies [66]. The consequence of this concern is not to abandon RCTs in health services research, but rather to emphasize process and not content standardization. With an emphasis on process, we may develop interventions that are sensitive to local contexts with a focus on promoting competence, and safeguarding local ownership and autonomous motivation also for the providers [67, 68].

The waiting list group design has some obvious weaknesses, e.g. measuring compliance to waiting as well as the effect of the intervention. Only 35% of those invited accepted to take part in the study, which might weaken the external validity of the study. If we experience unbalanced drop-out with a high attrition rate in the waiting list group, the internal validity of the study will obviously be affected. We have accounted for drop-out and have reached the number of participants recommended based on power calculations. The primary outcome measure will be objectively assessed, and validated tools will assess secondary and mediating variables. The research team possesses competencies in sports and nutrition sciences, general practice, nursing sciences and public health.

The results may also be relevant for other countries with comparable health care systems in the search for effective interventions for NCD targets.

Conclusion

A randomized trial of interventions in Healthy Life Centres has the potential to influence the development of policy and practice for behaviour change interventions and patient education programmes in Norway.

Abbreviations

CBT: Cognitive behavioural therapy; GP: General practitioner; HCCQ: Health care climate questionnaire; HLC: Healthy life centre; HRQoL: Health-related quality of life; METs: Metabolic equivalent of task; MI: Motivational interviewing; MRC: Medical research council; MVPA: Moderate-to-vigorous physical activity; NCD: Non-communicable disease; PA: Physical activity; RCT: Randomized controlled trial; SDT: Self-determination theory; TSRQ: Treatment self-regulation questionnaire

Acknowledgements

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Funding

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Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Authors' contributions

EA and GBS participated in the design of the study, took part in recruiting HLCs and drafted the manuscript. EM, TM, THS and SB participated in the design of the study, took part in recruiting HLCs and gave input on several drafts of the manuscript. All authors critically revised the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

Not applicable.

Ethics approval and consent to participate

All participants will sign an informed consent prior to participation in the study. The Regional Committee for Medical and Health Research Ethics (REK Vest) has approved the study (no. 2013/1291).

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Paper I search protocol

Systematic review of behavioural interventions on physical activity and dietary intake on overweight or obese adults[1]

Objectives

To systematically review behavioural interventions on physical activity and/or dietary intake in overweight/obese adults.

Criteria for considering studies for the review

Types of studies

RCTs of at least 12 weeks duration with follow-up data after the point of randomization.

Types of participants

Participants with a mean or median age for all groups of above 40 (no upper limit), and an average BMI for all groups combined of ≥ 30 at baseline.

Types of interventions

Behavioural interventions - general approaches

- BT
- CT
- CBT
- Psychotherapy
- Relaxation therapy
- Hypnotherapy

Subcategories of analysis:

- Behavioural intervention vs. Control
- Behavioural intervention + diet and/or exercise and/or pharmacological intervention vs. diet and/or exercise and/or pharmacological intervention only
- Behavioural intervention vs. different behavioural intervention

Studies scrutinizing behavioural interventions in participants taking antipsychotic drugs are excluded.

Types of outcome measures

[1] Criteria for considering studies is based on structures recommended by the Cochrane Collaboration (Avenell et al 2004) and later used by Dombrowski and associates (Dombrowski et al. 2012). The review has Dombrowski's search strategy as point of departure but adds smaller adjustments.

- Behaviour change in physical activity and/or diet (must).Subjective/objective measures.
- Secondary outcome: Behavioural change intervention characteristics (BTS) identified by a taxonomy[2,3].

Search strategy for identification of studies

1. **Electronic database searching**
   - Ovid MEDLINE ®
   - Ovid PsychINFO
   - Ovid Embase
2. **Handsearch**
   Int Jour of Obesity, Int Jour of behavioral nutrition and physical activity, Obesity research and clinical practice, and Int jour of behavioral medicine
3. **Relevant reviews**

Methods of the review

Identification of possible RCTs

Possible RCTs will be electronically imported into a reference managing software package (EndNote) and duplicates removed.

Titles

The titles will be independently screened by two researchers (GBS and EM) to test agreement on inclusion/exclusion and differences will be resolved by discussions. Thereafter, the identification of titles will be completed by one researcher (GBS).

Abstracts

Relevant abstracts of relevant titles published in peer-reviewed journals will be independently screened by two researchers. Where uncertainty remains the full paper will be examined.

Full text papers

[2] There are 3 taxonomies available; (Abraham and Michie 2008; Michie at al, 2011 and Michie et al, 2013).
[3] A BCT is defined[3] as "a replicable component of an intervention designed to alter or redirect causal processes that regulate behavior. A technique is proposed to be an 'active ingredient" (Michie et al. Implementation Science 2011, 6:10).
.

After screening by abstract, full text papers of potentially relevant studies will be screened to assess suitability for inclusion by 2 researhers. Length of the RCT is counted from randomization and includes the period of active intervention, however long, and period of follow-up. The study has to give a detailed description of the components of the intervention. If, for example, the study only reports that participants are asked to increase their level of exercise with no further details, this is not categorized as an exercise intervention. Inclusion criteria specify that intervention has to use cognitive or behavioral strategy, so interventions consisting of only provision of information will be excluded. Studies that state that they include a psychological intervention will not be include within the analysis unless the BCT is able to be identified.

Quality assessment of included studies

Finally, all included studies for the review will be assessed by 2 pairs of researchers for methodological quality using a standard form (The Cochrane risk of bias tool). The methodological quality will be assessed to identify potential bias in random sequence generation, allocation concealment, performance bias, blinding of outcome assessment, attrition bias, reporting bias and/or other bias (The Cochrane Handbook of Systematic Reviews of Interventions).

Data abstraction from included RCTs/coding of study characteristic

In the first few studies behavioural change techniques will be coded by 4 researchers until a common understanding and coding practice is established. Thereafter outcome data (sample sizes, means and standard deviations) and behavioural change techniques will be extracted by 2 pairs of researchers in cooperation (GW and EM) and (GBS and TB). Behavioural change intervention techniques will be extracted using a taxonomy. A coding manual is available. Interrater reliability check on identification of BCTs will be conducted. Disagreement will be resolved by discussion. All other identified study- and intervention characteristics will be collected by one researcher (GB). Reviews of characteristics of all included RCTS, features of the PA and diet interventions and outcomes, will be screened by 2 researchers. Scoring of frequency and behavioral change techniques will be done by 2 pairs of researchers.

Data analysis

Where results from studies can be quantitatively combined, a statistical meta-analysis of the data will be undertaken. For dichotomous data and odds ratio will be derived, and for continuous data a standardized mean difference will be calculated (weighted by the inverse of the variance). Analyses will use a fixed effects approach. Evidence for heterogeneity across studies will be explored using the chi-squared test for heterogeneity.

We will examine whether any of the following intervention characteristics are associated with intervention effectiveness: target behavior, number of intervention techniques, total number of

techniques, intensity/duration of intervention, source of delivery, format of delivery, treatment setting, time of outcome measurement, target population.

Reporting

The review will be conducted according to Cochrane Handbook and reported according to PRISMA guidelines.

1. Search in databases were conducted (2007-) 05.04.2013
2. Updated (2012-)18.09.2014
3. Handsearch journals August 2013-18.10.2014
4. Reviews checked until end of 2014.

Paper I search strategy

VI

Research strategy (Dokumentasjon av litteratursøk)

Tittel/Tema	Obesity (> 30 BMI),
Spørsmål fra PICO-skjema:	
Kontaktdetaljer for gruppen:	Gro Beate Samdal
Bibliotekar som utførte/veiledet søket:	Regina Küfner Lein

Oppdatering av søk i Medline, Embase og PsycINFO ble foretatt 18.9.2014, med samme søkestrategi som 5.4.2013. Avgrenset til publiseringsår 2012-current, for å sikre god nok overlapp og ikke gå glipp av studier publisert sent i 2012 som ikke var registrert i databasen i april 2013.
Medline (Ovid): 952 treff (avgrenset til engelsk)
Embase (Ovid): 2302 treff (ikke avgrenset på språk)
PsycINFO (Ovid): 306 treff (avgrenset til engelsk språk)
Etter fjerning av dubletter: totalt 2710 artikler i oppdateringssøket.
Etter fjerning av dubletter med tidligere søk: 1715 nye artikler siden 5.4.2013

Litteratursøket ble utført 5. april 2013 i Medline, Embase og PsycINFO i samarbeid med Universitetsbiblioteket i Bergen; søkestrategien er basert på Dombrowski (2012), men lett modifisert, og kan fåes ved henvendelse til forfatteren. Modifikasjonene ble gjort for å sikre at studier på voksne og/eller mennesker ikke ble utelatt når de samtidig handlet om barn og/eller dyr. Søkefilteret for psykologiske intervensjoner ble utvidet med termen motiv* interview*, dessuten ble søkeresultatene kombinert med søketermer for diett eller fysisk aktivitet. Søket er avgrenset til studier publisert fra 2007 til søkedatoen.

Database/ressurs:	Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1946 to Present
Dato for søk:	5.4.2013
Søkehistorie:	1 Obesity/ (114412) 2 obesity, abdominal/ or obesity, morbid/ (10978) 3 hyperphagia/ or bulimia/ (6809) 4 obes*.tw. (154563) 5 weight loss.tw. or exp Weight Loss/ (60262) 6 overweight.tw. (32621) 7 (weight adj1 (maint* or reduc*)).tw. (10742) 8 (los* adj1 weight).tw. (52502) 9 (diet* adj5 weight).tw. (12147) 10 (weight adj1 control).tw. (4120) 11 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 (251118) 12 limit 11 to "all child (0 to 18 years)" (51707) 13 limit 11 to "all adult (19 plus years)" (110947) 14 12 and 13 (25817) 15 12 not 14 (25890) 16 11 not 15 (225228) 17 controlled clinical trial.pt. (85685) 18 Randomized controlled trial.pt. (346301) 19 Randomized Controlled Trial/ (346301) 20 Random Allocation/ (76911) 21 Double-Blind Method/ (119155) 22 Single-Blind Method/ (17316)

	23 17 or 18 or 19 or 20 or 21 or 22 (502789) 24 clinical trial.pt. (476744) 25 exp clinical trial/ (712567) 26 ((singl* or doubl* or trebl* or tripl*) adj25 (blind* or mask*)).tw. (125555) 27 Placebos/ (31535) 28 placebo*.tw. (147925) 29 random*.tw. (641773) 30 Research Design/ (73473) 31 (clin* adj25 trial*).tw. (238534) 32 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 (1304523) 33 23 or 32 (1341810) 34 16 and 33 (29583) 35 Diet/ (101143) 36 (healthy eating or diet*).tw. (358830) 37 35 or 36 (394758) 38 exp Exercise/ (100859) 39 ((physical adj6 (exercise or activity)) or walk* or train*).tw. (405088) 40 38 or 39 (458187) 41 37 or 40 (828844) 42 34 and 41 (11712) 43 Psychotherapy/ (39578) 44 Mood Disorders/ (10109) 45 (psycho* or counsel*).tw. (451969) 46 (depression or depressiv*).tw. (225179) 47 (interpersonal adj5 therap*).tw. (756) 48 (art therap* or aversion therap* or balint* or behavio?r therap* or behavio?r modific* or colo?r therap*).tw. (7942) 49 ((cognitiv* adj5 therap*) or crisis intervention* or dance therap* or gestalt therap* or music therap* or milieu therap*).tw. (13850) 50 ((assert* adj5 training) or (nondirectiv* therap* or non directiv* therap*)).tw. (370) 51 ((problem solving or problemsolving) adj5 therap*).tw. (350) 52 ((self control or selfcontrol) adj5 therap*).tw. (57) 53 (person cent* or client cent* or (psychodrama* or psycho drama*) or paradoxic* techni*).tw. (2248) 54 (play therap* or rational emoti* or reality therap* or role play* or (relax* adj5 train*)).tw. (15230) 55 (sociotherap* or socio therap* or (socioenvironment* or socio environment*) or supportiv* therap* or transactional or behavio?r*).tw. (706597) 56 (motiv* adj1 interview*).tw. (1580) 57 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 (1270191) 58 42 and 57 (2601) 59 limit 58 to yr="2007 -Current" (1432)
Antall treff:	1432 (overført til EndNote, etter fjerning av dubletter innen Medline 1333 referanser)
Kommentarer:	Tw. = titel or abstract

	Mp. = [mp=title, original title, abstract, name of substance word, subject heading word] Randomized Controlled Trial/ MeSH is actually the publicatontype pt and covered already “obesity in diabetes” som I Dombrowski var oppført som MeSH, finnes ikke som MeSH Research design.sh fra Dombrowski 2012 er det samme som MeSH research design/ (= MeSH, ikke eksplodert) Ekskludere studier om barn (modifisert Dombrowski 2012): 12. limit 11 to "all child (0 to 18 years)" – studier om barn 13. limit 11 to "all adult (19 plus years)" – studier om voksne 14. 12 and 13 – studier om både barn og voskne 15. 12 not 14 – studier om barn, men ikke om barn og voksne 16. 11 not 15 – overvektsstudier, men ikke de om bare barn

Database/ressurs:	Ovid Embase 1974 to 2013 April 04
Dato for søk:	5.4.2013
Søkehistorie:	1 obesity/ or abdominal obesity/ or diabetic obesity/ or morbid obesity/ (232732) 2 hyperphagia/ (3508) 3 bulimia/ (10445) 4 obes*.tw. (208548) 5 weight reduction/ (82715) 6 overweight.tw. (44712) 7 (weight adj1 (maint* or reduc*)).tw. (14343) 8 (los* adj1 weight).tw. (70946) 9 (diet* adj5 weight).tw. (15317) 10 (weight adj1 control).tw. (5178) 11 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 (380375) 12 multicenter study/ (106334) 13 phase 2 clinical trial/ (39624) 14 phase 3 clinical trial/ (16362) 15 phase 4 clinical trial/ (1357) 16 randomized controlled trial/ (342198) 17 meta analysis/ (69974) 18 crossover procedure/ (36574) 19 double blind procedure/ (116395) 20 single blind procedure/ (17193) 21 randomization/ (61098) 22 placebo/ (228195) 23 drug comparison/ (131004) 24 clinical study/ (90561) 25 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 (924139) 26 (clin* adj25 trial*).tw. (317168) 27 ((singl* or doubl* or trebl* or tripl*) adj25 (blind* or mask*)).tw. (162563) 28 placebo*.tw. (192256) 29 random*.tw. (805758) 30 control*.tw. (2962023) 31 26 or 27 or 28 or 29 or 30 (3635924)

	32 25 or 31 (4047905) 33 nonhuman/ (4028717) 34 human/ (14197603) 35 33 and 34 (781596) 36 33 not 35 (3247121) 37 32 not 36 (3375592) 38 37 and 11 (99979) 39 limit 38 to (infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>) (14184) 40 limit 38 to (adult <18 to 64 years> or aged <65+ years>) (42253) 41 39 and 40 (5747) 42 39 not 41 (8437) 43 38 not 42 (91542) 44 exp diet/ (191039) 45 (healthy eating or diet*).tw. (442968) 46 44 or 45 (502218) 47 exp exercise/ (193036) 48 exp physical activity/ (204128) 49 ((physical adj6 (exercise or activity)) or walk* or train*).tw. (511531) 50 47 or 48 or 49 (750512) 51 46 or 50 (1211363) 52 43 and 51 (30435) 53 Psychotherapy/ (77834) 54 Mood Disorders/ (23650) 55 (psycho* or counsel*).tw. (632738) 56 (depression or depressiv*).tw. (297644) 57 (interpersonal adj5 therap*).tw. (1073) 58 (art therap* or aversion therap* or balint* or behavio?r therap* or behavio?r modific* or colo?r therap*).tw. (12213) 59 ((cognitiv* adj5 therap*) or crisis intervention* or dance therap* or gestalt therap* or music therap* or milieu therap*).tw. (20826) 60 ((assert* adj5 training) or (nondirectiv* therap* or non directiv* therap*)).tw. (553) 61 ((problem solving or problemsolving) adj5 therap*).tw. (493) 62 ((self control or selfcontrol) adj5 therap*).tw. (109) 63 (person cent* or client cent* or (psychodrama* or psycho drama*) or paradoxic* techni*).tw. (3164) 64 (play therap* or rational emoti* or reality therap* or role play* or (relax* adj5 train*)).tw. (19126) 65 (sociotherap* or socio therap* or (socioenvironment* or socio environment*) or supportiv* therap* or transactional or behavio?r*).tw. (835553) 66 (motiv* adj1 interview*).tw. (2165) 67 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 or 64 or 65 or 66 (1609798) 68 52 and 67 (6456) 69 limit 68 to yr="2007 -Current" (3657)

Antall treff:	3657 treff, overført til EndNote (etter fjerning av dubletter innen EMBASE = 3484 referanser. Etter fjerning av dubletter med Medline = 2581 unike EMBASE-referanser)
Kommentarer:	Modifisert strategi til Dombrowski 2012 for å utelukke studier på bare barn og/eller dyr

Database/ressurs:	Ovid PsycINFO <1806 to April Week 1 2013>
Dato for søk:	5.4.2013
Søkehistorie:	1 obes*.mp. (21945) 2 hyperphagia*.mp. (1105) 3 binge eating.mp. (3877) 4 (bulimi* adj5 non-purging).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures] (28) 5 (weight adj1 loss).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures] (7233) 6 (weight adj1 control).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures] (4604) 7 overweight.mp. (7982) 8 (weight adj1 (maint* or reduc*)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures] (1919) 9 (diet* adj5 weight).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures] (2516) 10 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 (33403) 11 limit 10 to (100 childhood <birth to age 12 yrs> or 120 neonatal <birth to age 1 mo> or 140 infancy <age 2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs>) (7669) 12 limit 10 to "300 adulthood <age 18 yrs and older>" (15926) 13 11 and 12 (2967) 14 11 not 13 (4702) 15 10 not 14 (28701) 16 animal.po. (291450) 17 human.po. (2830002) 18 16 and 17 (24798) 19 (animal not (animal and human)).po. (266652) 20 (15 not (animal not (animal and human))).po. (25254) 21 (clin* adj25 trial*).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures] (26736) 22 ((singl* or doubl* or trebl* or tripl*) adj25 (blind* or mask*)).mp. [mp=title, abstract, heading word, table of contents, key concepts, original title, tests & measures] (19195) 23 placebo*.mp. (29142) 24 random*.mp. (118201)

	25 control*.mp. (466474) 26 21 or 22 or 23 or 24 or 25 (559278) 27 20 and 26 (10088) 28 diets/ (8230) 29 (healthy eating or diet*).tw. (27860) 30 28 or 29 (28474) 31 exp physical activity/ (20760) 32 ((physical adj6 (exercise or activity)) or walk* or train*).tw. (257299) 33 31 or 32 (264771) 34 30 or 33 (288529) 35 27 and 34 (3951) 36 Psychotherapy/ (40206) 37 Mood Disorders/ (10720) 38 (psycho* or counsel*).tw. (867693) 39 (depression or depressiv*).tw. (188535) 40 (interpersonal adj5 therap*).tw. (2487) 41 (art therap* or aversion therap* or balint* or behavio?r therap* or behavio?r modific* or colo?r therap*).tw. (21341) 42 ((cognitiv* adj5 therap*) or crisis intervention* or dance therap* or gestalt therap* or music therap* or milieu therap*).tw. (31006) 43 ((assert* adj5 training) or (nondirectiv* therap* or non directiv* therap*)).tw. (1896) 44 ((problem solving or problemsolving) adj5 therap*).tw. (728) 45 ((self control or selfcontrol) adj5 therap*).tw. (218) 46 (person cent* or client cent* or (psychodrama* or psycho drama*) or paradoxic* techni*).tw. (7262) 47 (play therap* or rational emoti* or reality therap* or role play* or (relax* adj5 train*)).tw. (18070) 48 (sociotherap* or socio therap* or (socioenvironment* or socio environment*) or supportiv* therap* or transactional or behavio?r*).tw. (683011) 49 (motiv* adj1 interview*).tw. (1872) 50 motivational interviewing/ (1001) 51 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 (1480672) 52 35 and 51 (2528) 53 limit 52 to yr="2007 -Current" (1123)
Antall treff:	1123 treff, overført til EndNote (etter fjerning av dubletter innen PsycINFO = 1123 referanser. Etter fjerning av dubletter med Medline og Embase 574 unike fra PsycINFO)
Kommentarer:	Modifisert søkestrategi for å utelukke barn, dyr. Se kommentar i PsycINFO: For records added to the database prior to 1997, a document which includes both animal and human subjects are specified as "animal." From 1997 on, both "animal" and "human" is specified when both subjects are included.

Informed concent

VII

Forespørsel om deltakelse i et forskningsprosjekt

Bakgrunn

Vi inviterer deg til å være med i en undersøkelse for å evaluere Frisklivssentralens (FLS) tilbud til voksne som ønsker å endre levevaner. Alle deltakere på 7 FLSer får denne invitasjonen. Hensikten er å undersøke hvilken nytte deltakerne har av tilbudet. Bidrar det til sunnere kosthold, mer fysisk aktivitet, bedre livskvalitet og helse på kort og lang sikt? Universitetet i Bergen som er ansvarlig for forskningsstudien samarbeider med Universitetet i Agder og flere Frisklivssentraler om undersøkelsen.

Hva innebærer det å være med i studien?

Du må fylle ut spørreskjema, måler vekt og midjemål, går med en bevegelsesmåler på armen (måler aktivitet) og registrerer din søvn i løpet av 1 uke. Vi samler inn opplysninger ved start, etter 6 mnd og etter 18 eller 24 måneder. Spørreskjemaet tar ca. 30 minutter å besvare og alle dine opplysninger blir behandlet konfidensielt. I undersøkelsen sammenlignes en gruppe som deltar på frisklivssentralen med en gruppe som står på venteliste for tilbud. For at sammenlikningen skal bli vitenskapelig korrekt, trekker vi lodd om hvem som venter 6 måneder og hvem som får tilbudet med det samme. Flere FLSer har noe ventetid før du får plass, selv om du sier nei til å delta i forskningen. Deltakelsen vil derfor for noen gi økt ventetid, for andre kortere tid. Deltakelse medfører ellers ingen ulemper.

Hva skjer med informasjonen om deg?

Alle opplysninger om deltakere behandles uten navn og fødselsnummer. Vi erstatter navnene med en kode. Det er kun noen få personer ansatt i prosjektledelsen som ser navnelisten og som kan finne tilbake til den enkelte deltaker. Informasjon om personers identitet slettes når undersøkelsen er ferdig i 2017, og det er ikke mulig å identifisere noen når resultatene publiseres.

Frivillig deltakelse

Det er frivillig å delta i forskningsundersøkelsen. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke tilbake og dette vil ikke få konsekvenser for deg. Dersom du ønsker å hjelpe til med denne undersøkelsen, undertegner du samtykkeerklæringen på neste side. Dersom du seinere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Gro Beate Samdal (90073052) og Eivind Meland (90821975).

Samtykke til deltakelse i Frisklivsundersøkelsen

Jeg er villig til å delta

(Signatur deltaker, dato)

Navn med blokkbokstaver og mobilnummer

Survey

VIII

Study 2 Survey

Hvorfor ønsker du å delta på Frisklivssentralens/Frisklivs- og mestringssenterets tilbud? Sett kryss for 1-5 årsaker som passer deg best.

(1) ❑ Fysisk aktivitet
(2) ❑ Kostholdsendring
(3) ❑ Overvekt
(4) ❑ Muskel-/skjelett utfordringer
(5) ❑ Psykiske utfordringer
(6) ❑ Diabetes
(7) ❑ Høyt blodtrykk
(8) ❑ Hjerte-/karsykdom
(9) ❑ Lungesykdom
(10) ❑ Tobakkslutt
(11) ❑ Påtrykk fra andre (lege, arbeidsgiver, venner, familie)
(12) ❑ Annet

Hvor høy var din husholdnings samlede bruttoinntekt i fjor?
Ta med inntekt fra arbeid, NAV, stønad og lignende.
(1) ❑ Under 201.000 kr
(2) ❑ 201.000-300.000 kr
(3) ❑ 301.000-400.000 kr
(4) ❑ 401.000-550.000 kr
(5) ❑ 551.000-700.000 kr
(6) ❑ 701.000-850.000 kr
(7) ❑ over 850.000 kr

Hvilken utdanning er det høyeste du har fullført?
(1) ❑ Grunnskole 7-10 år
(2) ❑ 1-2 år videregående- eller yrkesskole
(3) ❑ Videregående skole med studiekompetanse
(4) ❑ Høyskole/Universitet, mindre enn 4 år
(5) ❑ Høyskole/Universitet, 4 år eller mer

Hva er din hovedaktivitet? Sett inntil 2 kryss.

(1) ❑ Yrkesaktiv
(2) ❑ Pensjonist
(3) ❑ NAV stønad
(4) ❑ Fullt sykemeldt
(5) ❑ Delvis sykemeldt
(6) ❑ Student/militærtjeneste
(7) ❑ Annet

Her følger ett spørsmål om din helse. **Hvordan vil du vurdere din egen helse, fysisk og psykisk?**

(1) ❑ Dårlig
(2) ❑ Nokså god
(3) ❑ Verken god eller dårlig
(4) ❑ God
(5) ❑ Veldig god

Se på disse påstandene og sett ett kryss fra 1-7 på det som passer deg best.

	1 Stemmer ikke i det hele tatt	**2**	**3**	**4**	**5**	**6**	**7 Stemmer helt**
Jeg har god selvfølelse	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Jeg opplevde å være verdsatt og respektert i min oppvekst	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑

Her er utsagn som beskriver forholdet til kroppen din.

	Aldri	**Sjelden**	**Av og til**	**Ofte**	**Vanligvis**
Jeg opplever kroppen min som en følelsesløs ting	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
Jeg føler meg vel i kroppen min	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
Det er lett for meg fysisk å slappe av	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
Kroppen min kjennes fremmed, som om den ikke tilhører meg	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
Min kropp er en trussel for meg	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑

	Aldri	Sjelden	Av og til	Ofte	Vanligvis
Jeg føler meg anspent i kroppen min	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
Det skjer ting i kroppen min som skremmer meg	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑

Er det noe ved kroppen din du har lyst å forandre?

(1) ❑ Ja
(2) ❑ Nei

Hva synes du om kroppen din?

(1) ❑ Altfor tynn
(2) ❑ Litt for tynn
(3) ❑ Omtrent passe størrelse
(4) ❑ Litt for tykk
(5) ❑ Altfor tykk
(6) ❑ Jeg tenker ikke på det

Prøver du å redusere vekten din?

(1) ❑ Nei, vekten min er passe
(2) ❑ Nei, men jeg tror jeg trenger å slanke meg
(3) ❑ Nei, jeg trenger å legge på meg
(4) ❑ Ja

Her er en skala fra 0-10 som kan illustreres med en stige. Generelt sett, hvor står du på stigen nå for tiden? 0 er verst mulig liv, 10 er best mulig liv

(1) ❑ 10 Best mulige liv
(2) ❑ 9
(3) ❑ 8
(4) ❑ 7
(5) ❑ 6
(6) ❑ 5
(7) ❑ 4
(8) ❑ 3
(9) ❑ 2
(10) ❑ 1

(11) ❑ 0 Verst mulige liv

Hvordan passer disse påstandene for deg generelt? Kryss av fra 1-7 for disse påstandene.

	1 Stemmer aldri	2	3	4 Stemmer av og til	5	6	7 Stemmer alltid
Jeg ser frem til hver eneste nye dag	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Jeg føler meg nesten alltid klar og våken	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Jeg føler jeg har mye energi	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑

Hvordan passer disse påstandene for deg? Sett ett kryss som beskriver din situasjon i løpet av den siste uken.

	Stemmer aldri	Stemmer sjelden	Stemmer av og til	Stemmer vanligvis	Stemmer alltid
På grunn av vekten min har jeg problemer med å plukke opp ting	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
På grunn av vekten min har jeg problemer med å komme meg opp av stoler	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
På grunn av vekten min har jeg problemer med å gå i trapper	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
På grunn av vekten min har jeg problemer med å kle av og på meg	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
På grunn av vekten min har jeg problemer med å bevege meg	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
På grunn av vekten min er jeg opptatt av hva andre tenker om meg	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
På grunn av vekten min er ikke selvfølelsen min hva den kunne ha vært	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑

	Stemmer aldri	Stemmer sjelden	Stemmer av og til	Stemmer vanligvis	Stemmer alltid
På grunn av vekten min er jeg usikker på meg selv	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
På grunn av vekten min er jeg redd for å bli avvist	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑

Her er to spørsmål om hvor mye du er i bevegelse. Inkluder all fysisk aktivitet, for eksempel å gå til butikken, til bussen, ta trappen i stedet for heisen, gå en tur, trene eller svømme.

Hvor lenge er du fysisk aktiv i gjennomsnitt i hver dag?

(1) ❑ Mindre enn 10 minutter hver dag
(2) ❑ 11-20 minutter hver dag
(3) ❑ 21-40 minutter hver dag
(4) ❑ 41-60 minutter hver dag
(5) ❑ Mer enn 60 minutter hver dag

Hvor hard er vanligvis din mest anstrengende fysiske aktivitet?

(1) ❑ Tar det rolig uten å bli andpusten og svett
(2) ❑ Blir litt andpusten og svett
(3) ❑ Blir avgjort andpusten og svett
(4) ❑ Tar meg nesten helt ut

Vær vennlig å se på følgende påstander og sett kryss ved det som passer best for deg.

	Helt uenig	Litt uenig	Litt enig	Helt enig
Jeg kjenner til aktuelle steder/tilbud for fysisk aktivitet som kan være aktuell for meg (for eksempel gå/sykle/trene/svømme eller annen aktivitet)	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Jeg benytter meg av en eller flere aktuelle steder/tilbud for å være fysisk aktiv	(1) ❑	(2) ❑	(3) ❑	(4) ❑

Tenk deg alle former for fysisk aktivitet og trening. Ta stilling til påstandene og sett kryss fra 1-7:

Jeg er sikker på at jeg kan gjennomføre planlagt fysisk aktivitet selv om:

	1 Ikke sikker i det hele tatt	2	3	4	5	6	7 Veldig sikker
- jeg er trett	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
- jeg føler meg nedtrykt	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
- jeg er bekymret	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
- jeg er sint på grunn av noe	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
- jeg føler meg stresset	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
- familien/ partneren min tar mye av tiden min	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
- været er dårlig	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
- jeg fremdeles har mye arbeid å gjøre	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑

Her følger noen spørsmål om støtte til fysisk aktivitet fra venner/bekjente/familie.

Har dine venner/bekjente/familiemedlemmer:

	Aldri	Sjelden	Noen få ganger	Ofte	Veldig ofte	Vet ikke
- foreslått at dere skulle drive fysisk aktivitet sammen?	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑
- oppmuntret deg til å være fysisk aktiv?	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑
- gitt deg hjelpsomme påminnelser om fysisk aktivitet som: «Skal du mosjonere i kveld»?	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑
- forandret planene sine slik at dere kunne drive fysisk aktivitet sammen?	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑
- sagt at fysisk aktivitet vil være bra for helsen din?	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑
- snakket om hvor godt de liker å være fysisk aktive?	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑

	Aldri	Sjelden	Noen få ganger	Ofte	Veldig ofte	Vet ikke

Her følger noen spørsmål om ditt kosthold. **Vanligvis, hvor ofte spiser du følgende matvarer?**

Frukt, bær og grønnsaker. Svar ENTEN per uke ELLER per dag.

		Gang per uke				Gang per dag			
	Aldri	Mindre enn 1	1-2	3-4	5-6	Mindre enn 1	1-2	3-4	5+
Frukt og bær	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
Grønnsaker	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑

Drikke. Svar ENTEN per uke ELLER per dag.

		Gang per uke				Gang per dag			
	Aldri	Mindre enn 1	1-2	3-4	5-6	Mindre enn 1	1-2	3-4	5+
Vann (springvann, flaskevann)	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
Brus med sukker	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
Lettbrus	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
Fruktjuice	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑

Snacks, snop eller søtsaker. Svar ENTEN per uke ELLER per dag.

		Gang per uke				Gang per dag			
	Aldri	Mindre enn 1	1-2	3-4	5-6	Mindre enn 1	1-2	3-4	5+
Sjokolade, godteri	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
Salt snacks (potetgull o.l.)	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
Kjeks, kaker, boller o.l.	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑

	Gang per uke					Gang per dag			
	Aldri	**Mindre enn 1**	**1-2**	**3-4**	**5-6**	**Mindre enn 1**	**1-2**	**3-4**	**5+**
Gatekjøkkenmat (hamburger, kebab, pommes frites, pølse o.l.)	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑

Nøtter. Svar ENTEN per uke ELLER per dag.

	Gang per uke					Gang per dag			
	Aldri	**Mindre enn 1**	**1-2**	**3-4**	**5-6**	**Mindre enn 1**	**1-2**	**3-4**	**5+**
Nøtter	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑

Meieriprodukter. Svar ENTEN per uke ELLER per dag.

	Gang per uke					Gang per dag			
	Aldri	**Mindre enn 1**	**1-2**	**3-4**	**5-6**	**Mindre enn 1**	**1-2**	**3-4**	**5+**
Fettrike meieriprodukter (f.eks helmelk, fløte, seterrømme o.l.)	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
Magre meieriprodukter (f.eks skummet melk, ekstra lettmelk, lett yoghurt o.l.)	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑

Fisk og kjøtt. Svar ENTEN per uke ELLER per dag.

	Gang per uke					Gang per dag			
	Aldri	**Mindre enn 1**	**1-2**	**3-4**	**5-6**	**Mindre enn 1**	**1-2**	**3-4**	**5+**
Fisk	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
Rødt kjøtt (storfe, svin, sau/lam, geit, kjøttdeig, pølser, hamburgere o.l.)	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
Hvitt kjøtt (kylling, høne, kalkun o.l.)	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑

Olje (oliven-, rapsolje og Vita hjertego). Svar ENTEN per uke ELLER per dag.

	Gang per uke					Gang per dag			
	Aldri	**Mindre enn 1**	**1-2**	**3-4**	**5-6**	**Mindre enn 1**	**1-2**	**3-4**	**5+**
Olje (til steking, i salater eller til andre formål)	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑
	(0) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑	(0.5) ❑	(1.5) ❑	(3.5) ❑	(5.5) ❑

Hvor ofte pleier du å spise følgende måltider i løpet av en uke?

	Aldri	**Mindre enn 1**	**2**	**3**	**4**	**5**	**6**	**7**
Frokost	(8) ❑	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Formiddag/lunsj	(8) ❑	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Middag	(8) ❑	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Kveldsmat	(8) ❑	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Nattmat	(8) ❑	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑

Påstandene nedenfor handler om matvaner og sultfølelse. Sett kryss for svaret som passer best for deg.

	Stemmer ikke i det hele tatt	Stemmer ikke særlig bra	Stemmer ganske bra	Stemmer helt
Jeg tar med hensikt små porsjoner for å holde kroppsvekten nede	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Når jeg føler meg urolig, oppdager jeg ofte at jeg spiser	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Av og til når jeg begynner å spise, er det akkurat som om jeg ikke klarer å slutte	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Når jeg føler meg nedstemt, spiser jeg ofte for mye	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Jeg unngår visse typer mat fordi de er fetende for meg	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Når jeg er sammen med andre som spiser, får jeg selv ofte lyst på mat og begynner å spise	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Jeg får ofte så lyst på mat at magen føles som et stort hull som ikke kan fylles	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Jeg har alltid lyst på mat, så det er vanskelig for meg å slutte å spise før jeg har spist opp alt på tallerkenen	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Når jeg føler meg ensom, trøster jeg meg selv med å spise	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Jeg holder bevisst igjen ved måltidene for ikke å gå opp i vekt	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Når jeg kjenner lukten av deilig mat, er det vanskelig å la være å spise selv om jeg akkurat har avsluttet et måltid	(1) ❑	(2) ❑	(3) ❑	(4) ❑

	Stemmer ikke i det hele tatt	Stemmer ikke særlig bra	Stemmer ganske bra	Stemmer helt
Jeg har alltid lyst på noe å spise, så jeg kan spise når som helst	(1) ❑	(2) ❑	(3) ❑	(4) ❑

	Nesten aldri	Sjelden	Ofte	Nesten alltid
Når jeg ser noe som ser veldig godt ut, får jeg ofte så lyst på det at jeg må spise med en gang	(1) ❑	(2) ❑	(3) ❑	(4) ❑
Hvor ofte unngår du å ha fristende mat tilgjengelig?	(1) ❑	(2) ❑	(3) ❑	(4) ❑

Hvor sannsynlig er det at du bevisst spiser mindre enn det du vil ha?

(1) ❑ Usannsynlig
(2) ❑ Ikke særlig sannsynlig
(3) ❑ Ganske sannsynlig
(4) ❑ Veldig sannsynlig

Fortsetter du å spise selv om du ikke er sulten lenger?

(1) ❑ Aldri
(2) ❑ Sjelden
(3) ❑ Iblant
(4) ❑ Minst en gang i uken

Hvor ofte har du lyst på mat?

(1) ❑ Bare til måltidene
(2) ❑ Iblant mellom måltidene
(3) ❑ Ofte mellom måltidene
(4) ❑ Nesten alltid
(5) ❑ Nesten aldri

På en skala fra 1 til 8, der 1 står for ingen begrensning (spiser hva jeg vil, når jeg vil) og 8 står for streng begrensning (begrenser alltid matinntaket, gir aldri etter), hvor på skalaen befinner du deg?

(1) ❑ Spiser hva jeg vil når jeg vil

(2) ❑ 2
(3) ❑ 3
(4) ❑ 4
(5) ❑ 5
(6) ❑ 6
(7) ❑ 7
(8) ❑ Begrenser alltid matinntaket, gir aldri etter

Røyker eller snuser du? Sett inntil 2 kryss.

(1) ❑ Ja, røyker daglig
(2) ❑ Ja, røyker av og til
(3) ❑ Ja, snuser daglig
(4) ❑ Ja, snuser av og til
(5) ❑ Nei

Det er forskjellige grunner til at mennesker gjør som de gjør. Følgende påstander handler om dine grunner for å begynne å endre levevaner (for eksempel spise sunt, være mer fysisk aktiv, slutte å røyke) eller fastholde endrede levevaner over tid. Kryss av fra 1-7 for disse påstandene.

Grunner til at jeg ønsker å endre eller fastholde endrede levevaner er:

	1 Stemmer aldri	2	3	4 Stemmer av og til	5	6	7 Stemmer alltid
Fordi jeg ønsker å ta ansvar for min egen helse	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi jeg får dårlig samvittighet hvis jeg ikke gjør det	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi jeg personlig tror det er det beste for helsen min.	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi andre vil bli skuffet over meg hvis jeg ikke gjør det	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Jeg tenker ikke så mye på det	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi jeg har tenkt grundig gjennom det og tror det er viktig for mange sider ved livet mitt	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑

	1 Stemmer aldri	2	3	4 Stemmer av og til	5	6	7 Stemmer alltid
Fordi jeg ikke vil ha det bra med meg selv om jeg ikke gjør det	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi det er et viktig valg jeg ønsker å ta	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi jeg føler meg presset av andre til å gjøre det	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi det er lettere å gjøre som jeg blir fortalt enn å finne det ut selv	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi det passer med mine mål her i livet	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi jeg ønsker å bli godtatt av andre	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi det er veldig viktig for meg å leve så sunt som mulig	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Fordi jeg vil at andre skal se at jeg kan greie det	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑
Jeg vet ikke hvorfor jeg gjør det	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑	(6) ❑	(7) ❑

Ta stilling til følgende påstander og kryss av for det som best beskriver din situasjon i løpet av den siste tiden. **Når jeg får veiledning på hvordan jeg kan endre mine levevaner:**

	Stemmer aldri	Stemmer sjelden	Stemmer av og til	Stemmer vanligvis	Stemmer alltid
- har jeg en tendens til å ville gjøre det motsatte av hva de forventer av meg	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
- får jeg noen ganger lyst til å lukke ørene	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
- har jeg en tendens til å ville protestere	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
- hender det at jeg ikke bryr om hva de vil jeg skal gjøre	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑

Her følger noen spørsmål om ditt sosiale nettverk**.**

Hvor mange mennesker står deg så nær at du kan regne med dem hvis du har personlige problemer?

(1) ❑ Ingen
(2) ❑ 1-2 personer
(3) ❑ 3-4 personer
(4) ❑ 5-6 personer
(5) ❑ 7 personer eller mer

Hvor stor interesse viser folk for det du gjør?

(1) ❑ Ingen deltakelse eller interesse
(2) ❑ Lite deltakelse eller interesse
(3) ❑ Usikker
(4) ❑ Noe deltakelse eller interesse
(5) ❑ Stor deltakelse eller interesse

	Meget vanskelig	**Vanskelig**	**Mulig**	**Lett**	**Meget lett**
Hvor lett er det å få praktisk hjelp fra naboer eller andre om du skulle trenge det?	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑
Hvis du måtte be om hjelp fra andre, hvordan ville du oppleve det?	(1) ❑	(2) ❑	(3) ❑	(4) ❑	(5) ❑

Hvilke frisklivstilbud har du deltatt på? Kryss av ett eller flere tilbud

(1) ❑ Individuelle veiledningssamtaler, medberegnet mottaks- og avslutningssamtaler
(2) ❑ Gruppetilbud om kost og matvaner/Bra Mat kurs
(3) ❑ Gruppetilbud trening
(4) ❑ Gruppetilbud tobakkslutt
(5) ❑ Temamøter
(6) ❑ Samtalegrupper
(7) ❑ KID kurs (Kurs i mestring av depresjon)
(8) ❑ KIB kurs (Kurs i mestring av belastning)
(9) ❑ Annet

Over hvor lang tid deltok du på tilbud, målt i antall måneder fra første til siste møte med Frisklivssentralen/Frisklivs- og mestringssenteret? __

De siste påstandene vi ber deg ta stilling til er knyttet til dine møter med Frisklivssentralens eller Frisklivs- og mestringssenterets ansatte som veiledet deg på endring av levevaner.

Her omtales de som dine «veiledere». Forskjellige personer gjør dette på ulik måte. Knytt dine svar til én veileder, noen få eller alle. Sett ett kryss fra 1-7 på det som stemmer best med dine erfaringer.

	1 Stemmer aldri	2	3 Stemmer av og til	4	5	6	7 Stemmer alltid
Jeg opplevde at veileder(ne) ga meg valgmuligheter når det gjaldt mine levevaner	(1) ❑	(3) ❑	(4) ❑	(7) ❑	(8) ❑	(9) ❑	(10) ❑
Jeg følte at veileder(ne) forsto hva jeg mener og tenker om mine levevaner	(1) ❑	(3) ❑	(4) ❑	(7) ❑	(8) ❑	(9) ❑	(10) ❑
Veileder(ne) gjorde meg trygg på at jeg kan endre mine levevaner	(1) ❑	(3) ❑	(4) ❑	(7) ❑	(8) ❑	(9) ❑	(10) ❑
Veileder(ne) oppmuntret meg til å stille spørsmål	(1) ❑	(3) ❑	(4) ❑	(7) ❑	(8) ❑	(9) ❑	(10) ❑

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