Title: Weight Management in Primary Care: Scoping Review for Promising Interventions

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Running head: Obesity services review in primary care

Abstract

Background As more primary care (PC) organizations are working to better address obesity issues, it becomes important to identify and characterize the key elements of the most effective lifestyle interventions when offered in the context of overall medical management. Studies that met pre-defined criteria for clinical relevance that had been conducted in PC settings were narratively reviewed for promising approaches.

Methods Search terms from three concepts (obesity/overweight, non-drug treatments, and PC setting) were used to search PubMed, CINAHL, Cochrane CENTRAL, and Science Citation Index Expanded. Primary studies of any study design, published between 2003 and March 2012, were grouped by major disease/condition and assessed for pre-defined clinically relevant changes in intermediate and clinical outcomes. To aid in interpretation, study design and quality were assessed and key features of the studies summarized. Details of interventions by provider background, training for the intervention and delivery channel were catalogued.

Results The search yielded 280 unique intervention studies (including controlled clinical trials and pre-post studies), of which 156 (56%) were somewhat or very likely to be conducted in representative groups and had at least one clinically relevant change in an intermediate marker or disease incidence. Nearly half (46%) were diabetes treatment studies. Overall, only 19 studies of the 68 (28%) relevant studies in adults (excluding pregnancy) that assessed weight change achieved a mean weight loss of 3% or 1 BMI unit in the intervention group. Only in prediabetes and metabolic syndrome was modest weight loss associated with a decrease in diabetes incidence. The most successful interventions intensified lifestyle interventions through a combination of increased physician efforts, additional providers, protocols for

management, and a range of additional resources, mentoring and performance monitoring.

Conclusions This review of diverse implementation studies conducted in primary care confirmed that the most effective lifestyle programs can achieve modest changes in body weight in some clinical subgroups. Such modest changes are clinically relevant in the prediabetes/metabolic syndrome subgroup. The most promising studies provided insights to inform further implementation studies. Additional methodological work is also needed to determine best approaches for reviews of effectiveness of such complex interventions.

Keywords: patient care management; primary health care; delivery of health care; overweight; health behavior

Background

Primary care (PC) services in Canada and other countries with comparable health care systems are being challenged to implement lifestyle services (i.e., diet, physical activity, other behaviour change and combinations of these) to prevent and treat obesity across the life cycle. Several guidelines groups have promoted new lifestyle services in PC [1,2]. If services are to be increased, they will need to be integrated with the medical services already offered, such as prenatal care and management of common chronic conditions, like cardiovascular diseases (CVD). As noted by an Australian PC obesity research group, there is only sparse evidence on how results from clinical trials "can be translated into routine practice, and what systems may be necessary to ensure widespread adoption" [3]. Review of the current evidence is a first step to designing and testing new services in PC.

Obesity prevention and treatment are highly relevant to PC as the prevalence of excess

body weight has increased among both children and adults, and the associated common chronic conditions, notably diabetes, CVD and some cancers, are commonly treated in PC [4]. Substantial minorities of the adult population have prediabetes, hypertension and/or dyslipidemia. A significant minority of adults, (19% of adult Canadians (18+ years) and 40% of those 60+ years [5]), meet criteria for the cardiometabolic syndrome (MetS) (hypertension, visceral adiposity, dyslipidemia and hyperglycemia) and are at twice the risk of CVD, compared to those without that combination of risk factors [6]. Among large randomized clinical trials, the Diabetes Prevention Program (DPP) in the United States was notable in showing that lifestyle change was effective in reducing the incidence of diabetes [7,8], but most studies have failed to reduce mortality. The majority of care for all these conditions occurs in PC.

A number of systematic and other reviews of randomized clinical trials in specific diseases and for specific types of interventions have already been completed [9-11]. In brief, the majority of the current evidence base has been developed from studies conducted among volunteers from specialty clinics or in the community and then assessed for "relevance" to the PC setting, as was done in a recent review by the United States Preventive Services Task Force (USPSTF) [10]. Study selection criteria have varied widely. Key features of lifestyle interventions also vary widely and there are currently no broadly accepted ways of describing interventions.

A new review was therefore planned to identify promising approaches across the life span and spectrum of obesity prevention and treatment in PC. Various approaches to systematic review were considered, recognizing that methods are evolving rapidly [12-14]. Overall, the goal was to identify lifestyle studies conducted within PC, and then use quality assessment to interpret the results and identify potentially promising intervention components that could be trialed. Since

many evaluations in practice have pre-post designs, these were not excluded, if they met other criteria. The approach was aggregative rather than conceptual, and was intended to privilege generalizability over internal validity. Methods were adapted from the Cochrane Collaboration [15]. Therefore, documentation of the search strategy, screening and selection criteria, use of dual reviewers and the assessment of the quality of evidence of all studies were planned from the outset. In contrast to typical systematic reviews, however, multiple populations, interventions and study designs were to be reviewed using the same review process. A priori, criteria for clinically relevant change were established to focus efforts on identifying the most promising approaches.

Methods

Designing the Search Strategy - Search Terms and Phrases

A medical librarian with expertise in systematic reviews created a search strategy specific to each database. The search strategy for each database is shown in Additional file 1. Each database was searched using terms for three distinct concepts: obesity and overweight, non-drug treatments, and PC setting.

Included Electronic Databases

The electronic databases PubMed, CINAHL, Cochrane CENTRAL, and SCI-Expanded were searched for studies in English between January 2003 and March 2012. The timeframe was chosen to identify studies completed since a previous search for our group done by the Evidence-based Practice Centre at McMaster University [16]. All retrieved citations were exported, compiled and organized (including removal of duplicates) into one Reference Manager 12 file (http://www.refman.com).

Inclusion Criteria for Study Selection

Types of Participants

Age was not limited and the conditions of interest selected were overweight, obesity or any obesity-related co-morbid conditions (e.g., type 2 diabetes, hypertension, dyslipidemia, or CVD), where obesity prevention or treatment was relevant to manage the condition. Body weight status was as recorded by authors and followed one of the international definitions. Studies limited to a small subset of patients (<20 patients per group) were excluded.

Types of Settings

The study had to have been conducted in PC practice or in other settings (e.g., private practice, community centre, pharmacy) if the intervention could be replicated in PC. Thus, studies of cardiac rehabilitation or studies where volunteers were solicited by advertisements in waiting rooms or newspapers were excluded (see Additional file 2).

Types of Study Designs

Primary studies of any research design were selected in screening; however, only pre-post and stronger study deigns (i.e. randomized controlled trials (RCT) or controlled clinical trials) were reviewed in detail. Primary studies referenced from reviews (systematic or narrative), guidelines or grey literature were included if they met the criteria.

Types of Interventions and Outcome Measures

The studies had to include a lifestyle component (i.e., discuss diet and/or physical activity) in the intervention description, even if focused on overall medical management of the relevant condition. Studies could be selected if they reported weight or body mass index (BMI, kg/m^2) but did not discuss details of the lifestyle therapy. The purpose of this last criterion was to ensure the inclusion of the broader self-management studies for chronic conditions that usually included some form of diet and exercise component.

A priori, criteria for clinically relevant change were established, recognizing the rarity of

studies that report on disease incidence and/or mortality. All studies that reported disease incidence, prevalence or mortality were reviewed. Clinical relevance criteria for intermediate indicators were set by the research team after review of current practice guidelines (see Table 1).

Study Selection Process and Quality Assessment

Two researchers reviewed all titles and abstracts; any article marked for inclusion by either went on to full text review. Full text review, quality assessment and data abstraction were done by two people who resolved any disagreements by discussion.

A title and abstract screening tool, as well as a full-text screening tool were developed based on the participants, setting, intervention and outcomes measures, and specific exclusion criteria (Additional file 2). A coding manual was also developed to improve consistency among reviewers.

During the full-text screening process, relevant qualitative studies, descriptions of organizational innovations and reviews were put aside and references of these articles were screened by one researcher based on the title.

Quality assessment was completed in duplicate from the primary methodology paper for each study. The Quality Assessment Tool for Quantitative Studies (public health) was used to assess risk of bias, given the interest in multiple study designs (section 21.4) [15]. As a check on the initial selection of studies, only studies that were **somewhat or very likely** to be representative of the target population according to Question 1 of the tool, were considered further.

Summary Table Preparation

Study data for all aspects of interventions and results were entered into an Excel database for further review and selection of those achieving clinically relevant change in one or more of

the selected criteria. Studies were categorized according to health condition, study design and baseline levels of selected clinical indicators, where relevant, since participants with more extreme levels might respond to a greater degree than those with less extreme baseline levels (regression to the mean). Lifestyle only versus comprehensive management studies were considered together. Interventions were described according to providers' background, the degree of description of any training provided and the delivery channels used. Weight or BMI changes were described separately. Studies not meeting clinical criteria or identified with selection bias were also catalogued.

Results

Included Studies

The initial search yielded 48,830 titles and abstracts to be screened. Of these, 1726 (4%) met the initial eligibility criteria and were further reviewed (full-text screen) (Figure 1). An additional 91 citations were handpicked (from reviews or citations which were part of a larger study) and were screened. When 1817 full text papers were reviewed for relevance to PC, 1162 (64%) were excluded. Of the remaining, 280 unique intervention studies (428 citations) were included and underwent full text review, and 156 (56%) met criteria for representativeness and had at least one relevant change in a clinical indicator or reported disease incidence or mortality.

Geographically, US-based studies dominated (43%), followed by the UK (15%), Netherlands (8%), Australia (5%), and Canada (4%). The recent publication of several multi-country European studies, while small in number, is important as they involve much larger numbers of subjects across differing models of PC practice (2%) (Figure 2). The remaining 31 studies were conducted in a range of countries.

All studies were categorized into nine unique groups of comparable studies, as shown in

Figure 3. Most prominent were the 128 studies (46%) of type 2 diabetes treatment, followed by 44 studies (16%) among people at risk for or who already had clinical CVD. Studies of lifestyle change for health promotion and weight loss as a primary focus were put together (13%), with studies specifically focused on prediabetes or MetS also grouped (9%). Four tables are provided for each of the nine groups (Tables 2-5 for prediabetes/MetS and Additional files 3 to 10 for the other groups): a summary of the clinically relevant studies, a description of the interventions, reported weight or BMI changes, and the studies that had been screened out.

Among the 156 studies with at least one clinically relevant change, only three among the 25 prediabetes/MetS studies achieved significant declines in prevalence of MetS or incidence of diabetes, a key clinical outcome [19, 24, 28] (Table 2). Only two studies (Griffin et al [17] and Delaney et al [18]), assessed CVD incidence and/or mortality and neither showed a decline (Additional files 3 and 4). Only four clinically relevant studies were ranked as being of high methodological quality (Bo et al., [19], Griffin et al. [17] Davies et al. [20], Delaney et al. [18] (Table 2, Additional files 3 and 4).

Overall Results on Changes in BMI or Body Weight

Nineteen of the 68 adult studies that assessed body weight achieved losses of 3% or 1 BMI unit in the intervention groups (Table 4 and Additional files 3 to 7 and Additional file 9). Other outcomes like physical fitness or quality of life were not routinely assessed. Mean loss was close to the predefined criterion in 18 of 19 studies. Only the Iori et al. group [21] in Italy achieved greater mean loss, but their study may have captured only weight loss among the most successful patients. A large number of practices (n=228) were involved and physicians focused on weight loss among those with BMI≥27; many of whom had CVD risk factors or clinical CVD

[21]. Each physician submitted 10 patients and 6-month changes were reviewed. About 70% returned for the 6-month visit. Among returnees, weight declined by a mean of 5%.

Review by providers' background, training, and delivery channels used in the 19 most effective studies did not reveal any one group of key strategies that could be identified as important to successful implementation of services (Table 3 and Additional files 3 to 7 Tables 3-2, Table 4-2, Table 5-2, Table 6-2 and Table 7-2). All successful interventions involved intensification of services using behaviour change counselling principles over longer periods of time to address lifestyle in the context of overall medical management, consistent with the findings of other reviews [10,22].

Multiple groups have shown that lifestyle therapy can prevent diabetes [23], so these studies were reviewed in detail to identify possible promising approaches. Results for other diseases and conditions are available as Additional files 3-10. Only the most promising studies from these other diseases and conditions are narratively described.

Prediabetes /Metabolic Syndrome

The nine studies with relevant changes are shown in Table 2. There were five randomized controlled trials (RCTs), and four one-group cohorts, with two reporting on MetS/prediabetes prevalence and three on diabetes incidence. Table 3 shows intervention strategies, while Table 4 provides detail on study length and BMI/weight changes. Table 5 summarizes studies that did not meet criteria for clinically relevant change or were unlikely to be representative

The three studies reporting on diabetes incidence are reviewed first. The cohort report by Saaristo et al. [24] from Finland on a national program (FIN-D2D) was by far the largest (n=2798), reporting on the one-year results of a high risk group scoring 15 or more on the

FINDRISC diabetes screening tool who underwent a lifestyle program in primary care (n=400 practices). Interventions varied widely, depending on local circumstances, but were broadly based on the Diabetes Prevention Study (DPS) and included both group and individual appointments based on individualized behavioural counseling principles [25]. Average weight loss was modest (1.4% in males, 1.3% in females), but the 17.5% who lost 5% or more of body weight had a relative risk (RR) of 0.31 (95% CI, 0.16 to 0.59) of developing diabetes compared to those whose weight was stable. The interventions included emphasis on both diet and increased physical activity.

Studies by Sakane et al. [26] and Penn et al. [27] were much smaller RCTs. Sakane et al. [26] in Japan compared usual care to additional support of 4 group classes over 6 months, with biennial follow-up among people with impaired glucose tolerance (IGT) (n=254). Three-year results were nearly statistically significant even with the small sample size. Mean initial BMI was 24.8; much lower than other studies, in line with the differing diabetes risk profile of East Asians compared to Europeans. The study by Penn et al. [27] was a local site for the European Diabetes Prevention Study (EDIPS), which extended the DPS to different European populations with IGT. The sample size was limited (n=102) and subjects were followed quarterly for up to 5 years. A variety of approaches were used, primarily one-on-one counselling with discounts to local gym facilities. While not statistically significant, relative risk (RR) reduction was very similar to the DPS.

Two studies looked at reversion of MetS or prediabetes. Bo et al. [19] stands out as one of four methodologically strong studies in the entire review as assessed by the quality assessment tool. Conducted in Italy, they offered four group sessions in addition to medical management for MetS in middle-aged adults (45 to 64 years). Other providers, including medical specialists and

nutritionists, were involved. The odds ratio (OR) for having MetS at one year was 0.28 (95% CI, 0.18 to 0.44) in the intervention group. Mean weight loss in the intervention group was only 1%, but because of weight gain in the control group receiving usual care (from mean 81.3 kg to 82.9 kg), net change in weight was 3%.

Finally, Moore et al.[28] in Australia conducted a six-month wait-list trial on a group screened for risk factors of diabetes (IGT or impaired fasting glucose). There were 307 participants; 62% of the group identified as having prediabetes and by 6 months, 43% of the intervention group had reverted to normoglycemia compared with 26% of controls. The program has been manualized and consisted of six group sessions and individual follow-up, covering much of the same ground as the DPP.

Among the remaining four studies, three assessed different adaptations of the DPP; one in Germany [29] and the other two reports from the same group who developed the original DPP program [30,31]. These diverse studies, conducted in different countries, all included behavioural strategies to improve diet and physical activity, and achieved relatively consistent results. A range of interventions were used, most of which included group classes and intensified follow-up. Mean weight changes were very modest.

Diabetes

Of the 128 studies of type 2 diabetes, only 24 (19%) were judged as somewhat or very likely representative of PC patients and had reported clinically relevant changes, predominantly in glycated hemoglobin (A1C). Only Griffin et al [17] assessed CVD incidence. Sixteen of 24 studies were conducted with subjects with high baseline A1C levels, and eight among subjects with lower baseline levels. Of these 24 studies, 12 had also recorded weight change and five had

achieved clinically relevant weight change of 3% or more, as shown in Additional file 3.

Baseline A1C ≥ 9

Of the four RCTs, three (Rothman et al [32], Scott et al [33], Taylor et al[34]) assessed body weight, all were 9-12 months long and focused on overall medical management. Metabolic control was improved, with stable or slightly increased body weight.

Among the 12 remaining studies (controlled clinical trials, one group cohort database review) in poorly controlled diabetes that achieved reductions in A1C, two of five studies where weight was measured, achieved relevant weight loss. The Mayer-Davis et al. [35] three-group study results were of interest as weight loss was a focus of this 12-month clinical trial of medically underserved patients with long-standing diabetes in South Carolina. The intensive lifestyle program was based on the DPP, adapted to the local context. The "reimbursement" group received less intensive intervention in line with Medicaid funding and the control group received usual care. A1C improved in all three groups but could not be attributed to the weight loss intervention, as a chronic disease management program was also instituted over the same period of time. Net weight loss of 0.8 BMI units was achieved among those in the intensive program. A team with a Registered Dietitian (RD), specific training and both one-on-one counselling and groups were used. Only Boyd et al. [36] also achieved relevant clinical weight changes in the same range in a very small sample (n=48) of low-income patients. Researchers had partnered with a local YMCA, but only 48 of 130 eligible patients (37%) visited the YMCA on at least one occasion. The results highlight benefits in the minority who will undertake change, as well as challenges with uptake of exercise interventions in some groups. Certainly, some patients achieved modest weight loss, but until additional studies show otherwise, the most realistic weight goal for most patients with higher baseline A1c is weight

stabilization.

Baseline Hemoglobin A1C < 9

Of the eight remaining studies, the RCT by Griffin et al. [17] was part of the ADDITION trial of intensive medical and lifestyle management of screen-detected type 2 diabetes. As previously noted, CVD incidence was reported but non-significant (intervention: 13.5 per 1000 person-years vs. control: 15.9 per 1000 person-years). Overall weight loss in the intervention group was 2% and net weight loss by both groups was similar. The intervention varied in different settings, but consisted of specialized training of providers, a team approach and both one-on-one and group education.

Among the seven other studies, Davies et al. [20] was the only cluster RCT (DESMOND) and the third of four studies among the 156 to be considered methodologically strong. This UK group compared a group education program to "additional resources" control in 207 general practices at 13 PC sites. Newly diagnosed patients were referred to the program, while comparator control practices received additional funding to provide equivalent additional contact time with patients and used resources as they saw fit. Many control practices offered group sessions. Registered healthcare professionals received formal training to deliver the program and were supported by a quality assurance component of internal and external assessment to ensure consistency. The group program was six hours long, facilitated by two educators and was focused on lifestyle and self-management. After 12 months, both control and intervention groups decreased their A1C and other clinical outcomes significantly, and to a similar degree, except body weight. Intervention group mean A1C decreased from 8.3 to 6.8 % while control group mean decreased from 7.9 to 6.7 %. Mean body weight decreased by 3.0 kg in the intervention group and 1.9 kg in the control group. Considering the already high caliber of usual

diabetes care in the UK, where 59% of diabetics achieve A1C of less than 7.4%, it was argued that it may have been more difficult to show additional benefits of the structured program. The study is particularly noteworthy, as patients and providers were broadly representative, and both arms of the study achieved notable and clinically relevant changes. An additional qualitative study noted both benefits and challenges of group sessions and a range of orientations to self-management among patients, confirming the need for multiple delivery methods [37].

As in the study by Griffin et al. [17], screen-detected type 2 diabetes patients were the focus of the study by Janssen et al. [38], another sub-study of the ADDITION trial. Participating PC practices in the Netherlands (n=79) were randomized to usual care versus nurse-led intensive care to manage CVD risk factors. Nurses received additional training on promoting lifestyle and were authorized to adjust medication. Five visits were held in the first 12 weeks, followed by quarterly follow-up visits with the nurse and physician. Mean A1C levels declined in both control (7.4 to 6.5) and intensive groups (7.3 to 6.2) ($p<0.03$), as did other clinical markers. In addition, net change in BMI between intervention and control groups was 1.6 units.

Athyros et al. [39] instituted specific training of physicians in Greece with enhanced use of CVD risk calculation, lifestyle counselling and medication management in a mixed group of diabetes patients (n=578), some of whom already had clinical CVD. All clinical indicators improved markedly, including body weight, but the study was judged to be weak and the generalizability of the results was uncertain.

These diverse studies provide insight on key aspects to consider. Practice context appears to be critical. In Greece, significant improvement could be achieved by physician training alone, but team practice was already well established in the UK and the Netherlands at baseline. Patient characteristics may have also differed; a number of patients in Greece already

had CVD, while newly diagnosed or screen-detected diabetes patients may have been able to lose weight more readily than other groups reviewed. These studies used various combinations of additional providers, incentives, practice guidelines, new delivery methods and chronic disease management strategies; and achieved similar degrees of weight change.

Mixed Cardiovascular Disease Risk Studies

Of the 44 studies of subjects with diverse combinations of CVD risk factors or clinical disease, 12 RCTs, one controlled clinical trial, and one cohort study reported at least one clinically relevant change in LDL cholesterol, blood pressure or body weight (Additional file 4).

Delaney et al. [18] reported on the 10-year mortality outcomes of an early RCT of nurse-led medication and lifestyle management clinics with patients who had a clinical diagnosis of coronary heart disease in northern Scotland. No data on body weight or clinical markers were published. At 10 years, CVD events (myocardial infarction or CVD death) and total mortality were the same in intervention and control groups.

Four studies achieved clinically relevant weight changes (3 kg weight loss or 1 BMI unit decrease) as shown in Additional file 4. Appel et al.'s [40] group reported positive results of a health coaching intervention run outside of PC direct care, but PC physicians got reports on progress. Subjects had at least one CVD risk factor and access to a computer. Two treatment groups received intensive support for weight loss from health coaches; one got remote support (call centre) only, while the other group got remote support plus in-person groups and both were compared to a control group, who got a self-directed manual. Net weight loss between groups (intervention minus control) after 24 months was 1.3 BMI units (or about 4% of body weight).

In one of the few studies from Canada, Petrella et al. [41] conducted a randomized trial of a physical activity prescription for 284 older patients from 4 clinics (16 physicians). The

intervention consisted of exercise counselling and a physician-administered Step test and prescription of an exercise training target heart rate at baseline, 3 and 6 months. Patients were taught how to assess heart rate. Both exercise and control groups were given a list of available recreation facilities for physical activity participation in their community. BMI decreased by 2.1 BMI units in the intervention group and by 0.6 units in the control group. Tracking of physician time indicated counselling took an average of 12 minutes in the intervention group and 7 minutes in the control group. Such tracking provides important information on the intensity and feasibility of the intervention. Older people (> 65 years) capable of exercise were recruited. It is unclear to what degree the results might be generalizable as the sample was recruited opportunistically.

In Denmark, Willaing et al. [42] compared referral to a RD with physician counselling in a cluster RCT (n=503). About 68% completed one-year follow-up. Among completers, weight loss was achieved in both groups; RD counselling resulted in mean loss of 4.5 kg (1.1 BMI unit) versus 2.4 kg in the physician only group, but physicians were more likely to actively treat CVD risk factors with medication. Interventions were both conventional one-on-one counselling.

Finally, the one group cohort chart audit study by McTigue et al. [43] implementing the 12-week group-based DPP curriculum plus additional classes in one clinical centre provides some practical sense of expected success. Of 155 people referred to the program, 72 (43%) enrolled for the costed program. Weight loss averaged 5 kg, compared to weight gain of 0.2 kg among those who were referred but did not enroll. Weight loss was quite consistent at 1-2 BMI units across these diverse studies, which were all at least 12 months long.

Health Promotion/Weight Loss

Thirty-six primarily weight control and health promotion studies were identified, but only six (one RCT and five one group cohorts) met our criteria and are summarized in Additional file 5. The largest study was the Counterweight program, which began in 2000 in Scotland [44]. This study included 75% of subjects with co-morbidities, but the main focus was weight loss. Always conceived as a pre-post implementation study, the 2008 publication provided data on the 12- and 24-month outcomes. Program features included 6 months of training and mentoring of practice nurses and feedback to practices on program outcomes. The program was incorporated into 56 practices without additional funding. The intervention included six individual appointments (10–30 minutes each) or six group sessions (1 hour each) over a 3-month period, and then follow-up at 6, 9, 12, 24 months. The sample was large, with 1419 enrolled and involved for at least 12 months. Only 642 (55%) patients provided 12-month data. Mean change in BMI at 12 months among attendees was –1.1 units, with 31% maintaining ≥5% weight loss. This amounts to a mean weight loss of –3.0 kg. A 2012 update of wider implementation reported similar results [45].

As previously mentioned, the Iori et al. [21] group in Italy recruited a large number of practices (n=228) where physicians submitted 10 patients each and 6-month changes were reviewed. Among returnees, weight declined by 5% or more. The generalizability of the study is unclear in spite of the large sample size, as every practice has some patients who can achieve good results with lifestyle change.

Among the four remaining small studies Chang et al. [46] conducted an RCT among low income women involved in the Women's, Infants and Children (WIC) program in the US. This study was reviewed as the WIC program provides many primary health care services pre- and post-partum. Control group women lost weight, while intervention women gained weight.

Among these studies, the Counterweight program provides the most relevant information for planning purposes [44]. A variety of teaching materials, training and mentoring approaches were used to better support practice nurses to deliver the program.

Hypertension, Dyslipidemia and Other Studies

Tables for hypertension, dyslipidemia, complex chronic diseases, pediatrics and pregnancy are shown in Additional files 6-10. The number of studies recording body weight were small. No new promising strategies emerged from the review of these studies.

Discussion

Weight management in the PC context is typically only one of many competing priorities, as providers and patients work to provide medical care and support self-management for best health. Self-management training and support is already integral to most programs in diabetes and cardiovascular disease treatment, but may be less common in other areas. Excessive body weight can be conceptualized as a chronic and often progressive condition [4], and similar management principles may be helpful. Weight management could entail a range of goals, including weight loss, weight gain prevention, promotion of physical activity and improved mental health. The focus of this and many other reviews has been body weight change, but the results of the diabetes incidence studies suggest that other unmeasured factors may be more important, since mean weight change was so modest in those studies. Since disease incidence studies are very expensive, additional work is needed to identify more valid intermediate markers for health risk, that can be used in future implementation studies to assess and improve the effectiveness of such lifestyle programs. Different groups of providers could offer interventions

and formats or channels could differ.

To identify promising approaches, this systematic scoping review was undertaken to focus on the most promising studies to date, in the context of typical PC. Most studies were focused on diabetes and mixed CVD risk management. While the most promising studies with a lifestyle focus did achieve modest weight losses in the range of previous systematic reviews (3kg or 3% or 1 BMI unit) [10], narrative analysis of key features of the interventions did not reveal any one key intervention, partly because of the complexity of assessing relevant contextual and patient factors. Better and in common methods of describing such factors is needed.

The most promising approaches had multiple elements including clear processes for diagnosis and assessment, training of providers, enhanced scope of practice, quality control, sustained programming and follow-up, and were broadly based on principles for sustained health behaviour change. Additional studies, especially in prediabetes and metabolic syndrome where reduction in diabetes incidence has been shown, are needed to determine what combinations of strategies will be most effective in different PC systems.

Based on previous work by us and others [44,47,48], it was known from the outset that diabetes and CVD would be prominent conditions in PC, and that approximately 50% of people undertaking lifestyle change in PC drop-out of lifestyle change programs. Study subjects in all types of medical management studies tend not to be representative of all patients, but the problem is particularly challenging in behavioural interventions where active involvement of participants is key to successful results. In addition, there may be substantial differences in response to interventions by socio-demographic and other factors. For example, most specialist studies have been conducted mainly in women, yet substantial proportions of men are also overweight and obese and suffer from the attendant conditions. Therefore, we decided to review

only studies conducted in PC settings, in hopes that the subjects would be more representative as evaluated by the quality assessment tool, and the interventions more relevant to the PC context.

This issue of indirectness, or the extent to which the groups under study are representative of the population of interest, has been addressed by systematic review methodologists using the GRADE system, by making a consensus judgment. It has recently been noted that such judgments may be unreliable [49]. Further methodological work is needed to adequately address this issue. It is uncertain at this point whether choosing only studies in the setting of interest is an advance.

Operationalizing study selection for the PC setting proved to be somewhat difficult in practice, since "setting" is not a typical keyword for cataloguing and searching purposes. Review of study methods was necessary to select studies. Studies based on newspaper or community advertisement, conducted by specialist providers or centres could be excluded at study selection, but studies that were not clear on recruitment were more problematic. A second step was therefore taken in excluding studies at quality assessment that were deemed as either "not representative" or "can't tell" by reviewers. In all cases, two reviewers agreed on selection. In spite of these efforts, we expect that our selection of studies may or may not be supported by other reviewers. We have therefore supplied the lists of both included and excluded studies (see Additional file 11).

Most systematic reviews privilege RCTs, often excluding pre-post studies, a common and feasible study design in implementation research. It is generally accepted that internal validity is a primary concern in establishing efficacy, but this approach may be too limiting in considering generalizability, especially if the researchers have taken steps to avoid many of the common sources of bias. We therefore did not exclude on this criterion at the start of the review,

and instead considered all studies, but separated out studies by study design, recognizing the potential for bias and confounding in non-randomized contexts. Notably, some important studies, including the FIN-D2D [24] and Counterweight studies [44,45], were retained and offered excellent insight to the possible success of weight management programs in specific PC practice.

The severity of the patients' clinical conditions and medical management itself (including side-effects of medications), can be expected to affect outcomes of weight management in the context of overall medical management. We therefore attempted to categorize studies broadly by disease and secondly by severity. This was most obvious in the diabetes studies, where the focus of care for poorly controlled diabetes would necessarily be focused on control of blood glucose and blood pressure rather than weight, and where addition of medications would tend to increase body weight. One strength of this review was the focus on weight management in the context of the many chronic conditions routinely treated in PC.

Even with these efforts to compare studies within broad groupings, studies were very diverse, so that only broad conclusions are possible. Among all the studies, the reports of Davies et al. [20] in newly diagnosed diabetes in the UK (both control and intervention groups), Janssen et al. [38] in screen-detected diabetes in the Netherlands, and the Counterweight Program in the UK [50] achieved clinically relevant weight control in sizable samples. All three studies were large well-organized studies (two trials and one pre-post study) that used a comprehensive suite of intervention strategies. Other studies, such as Greaves et al. [51] and Moore et al. [52], also employed additional providers and multiple approaches, yet intervention subjects achieved less weight loss than control subjects. If there were flaws in these latter studies, they were not obvious in review. The results, however, remind us that additional work is required to describe

561 context and patients better, as well as determine which KEY aspects need to be included in any
562 future implementation studies.

563 The most promising results were achieved in prediabetes or screen-detected diabetes. We
564 have insufficient information to determine if clinically relevant modest weight loss is possible in
565 the majority of patients with poorly controlled diabetes, CVD risk factors, or chronic diseases.
566 Between 10 and 20% of patients were able to achieve relevant weight loss (3%) in some studies.
567 The Counterweight program achieved weight loss of ≥5% in only 13% of all enrolled subjects
568 [44], while in the FIN D2D assessment 17.5% achieved such weight loss [24]. This latter finding
569 is relevant, as it confirms previous findings that weight loss of this magnitude will be achieved
570 by a minority of subjects.

571 Missing from the literature were any studies on weight gain prevention in otherwise
572 healthy or overweight children and adults in PC. Few of the studies focused on this topic, but the
573 study of Bo et al. [19], a strong study of patients with MetS, was suggestive, in that the control
574 group gained substantial weight. Additional studies in this high-risk target group are needed.
575

576 ## Limitations

577 Like self-care services in chronic diseases, obesity management in PC is a difficult area to
578 tackle successfully, balancing additional services with their associated costs to achieve improved
579 health for the majority of patients. The major limitation of this and other literature reviews is
580 that the evidence base for formulating new services is relatively weak, with major gaps in our
581 knowledge. From this review it is clear that we need a better understanding of which key
582 components must be included in obesity management programs in PC, and how to ensure that
583 costly, ineffective services are avoided.

584 A modified review methodology was used. It drew from established systematic literature
585 review methods on quality and outcome assessment. Our choice to limit by pre-defined clinical
586 change criteria is only one approach, which required substantial work to first determine the
587 degree of expected change and then to tabulate across studies. Limiting the review to include
588 only RCTs would have substantially shortened the process, but a few important studies would
589 have been missed. In fact, most promising interventions we found were also methodologically
590 strong studies. There is a need to further develop review methods for implementation studies.
591 There were significant challenges in identifying studies located in PC, and a wide variety of
592 outcomes were assessed. A move to larger cluster randomized trials, with broad consensus on
593 key outcomes and methods of assessment would improve the evidence base.
594

595 ## Conclusions

596 Given the underlying difficulty of obesity management [34], we attempted to assess
597 whether the PC literature would yield new insights on promising interventions. A few studies
598 using intensive approaches were able to achieve weight losses in the range of those seen in
599 previous systematic reviews. The tactic of including all study designs and focusing on those
600 studies able to show relevant changes, suggested that comprehensive programs have the best
601 chance of success. The most promising studies intensified interventions through a combination
602 of increased physician efforts along with additional providers, well established protocols for
603 management, and a range of additional resources, mentoring and performance monitoring. The
604 review approach was helpful in identifying a few promising studies, which can provide the basis
605 for new intervention studies. It is premature to implement broad programs for obesity
606 management in PC until more cluster randomized trials are completed.

List of Abbreviations:

A1C = glycated hemoglobin

BMI = body mass index

BP = blood pressure

CVD = cardiovascular disease

DM = diabetes

DPP = Diabetes Prevention Program

DPS = Diabetes Prevention Study

IFG = impaired fasting glucose

IGT = impaired glucose tolerance

MD = physician

MetS = cardiometabolic syndrome

NP = nurse practitioner

PC = primary care

RCT = randomized controlled trial

RN = registered nurse

RR = relative risk

USPSTF = United States Preventive Services Task Force

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Author's contributions:

OO was involved in the conception of the review, the acquisition, analysis and interpretation of the data, and drafted the manuscript.
PB was involved in the conception of the review, the acquisition, analysis and interpretation of the data, and drafted the manuscript.
DR was involved in the acquisition, analysis and interpretation of data, and drafted the manuscript.

LB was involved in the analysis and interpretation of data.
JJM was involved in the conception of the review and the interpretation of data.
AME was involved in the analysis and interpretation of data.
TH was involved in the interpretation of data.
NK was involved in the conception of the study and the interpretation of data.
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Figure legends

Figure 1. Study Selection Process.

Figure 2. Location of Studies by Country. Other countries (11% or 31 studies): Denmark 3 studies; France 3; Greece 3; Ireland 3; Norway 3; Belgium 2; Brazil 2; China 2; Switzerland 2; both Australia and New Zealand 1; Austria 1; Chile 1; Korea 1; Mexico 1; Singapore 1; Taiwan 1; Turkey 1.

Figure 3. Number of Studies by Disease/Condition Focus (n=280)

928 **Table 1. Clinically Relevant Change Criteria in Intervention Groups**
929

	Mean Change	% Change	Source
Children			
BMI	Z score change varies by height and weight – all studies reviewed		U.S. Preventive Services Task Force (USPSTF) [10]
Adults			
Incidence of disease or mortality	All studies reviewed		
Reversion of Metabolic Syndrome	All studies reviewed		
Weight (kg)	3 kg	3	USPSTF [10]
BMI	1 Unit		
A1C (%)	1.0		Canadian Diabetes Association [53]
LDL-cholesterol		11	Cardiometabolic Risk Working Group [54]
Systolic Blood Pressure (mm Hg))	5	4	Cardiometabolic Risk Working Group [54]
Diastolic Blood Pressure (mm Hg)	4	4	Cardiometabolic Risk Working Group [54]

930

Table 2: At Risk for Diabetes or Metabolic Syndrome Studies Reporting Clinically Relevant Changes[1]

Author/Date	Overall QA[2]	Focus	Wt / BMI	A1C	Lipids LDL-C	SBP / DBP	Baseline LDL-C	Baseline SBP	Disease incidence	Representative[3]
Randomized Controlled Trials										
Bo et al., (2007)[19]	Strong	MetS, lifestyle	**xx**		x (TC)	x		143	Intervention versus control: MetS prevalence reduction: 70.4% to 34.9% vs. 72.3 to 66%; Odds Ratio for having MetS at end of study = 0.28 (95% CI, 0.18 to 0.44)	vl
Kulzer et al., 2009[29]	Moderate	Prediabetes, Adapted Diabetes Prevention Program [7]	**xx**	x		**xx**		142		sw
Moore et al. 2011 [28]	Moderate	Prediabetes; lifestyle counselling	**xx**		x	**xx**	2.9	129	Intervention versus control: 13% vs 7% developed DM 43% vs 26% normalized (p<0.01) 45% vs 67% remained pre-DM	sw
Penn et al., 2009 [27]	Weak	Impaired glucose tolerance, Diabetes Prevention Study lifestyle	x						Intervention versus control: Incidence DM 33/1000 person years (py) vs. 67/1000 py RR 0.45 (95% CI, 0.2 to 1.2, NS)	sw
Sakane et al., 2011 [26]	Weak	Impaired glucose tolerance, lifestyle counselling	x						Intervention versus control: DM Incidence 8.2% vs 14.8% over 3 years (NS, p=0.097)	sw
Cohort – One Group										
Bihan et al., (2009)[55]	Weak	MetS; lifestyle			**xx** (HDL)	**xx**		142		sw
Kramer et al., (2009) [31]	Weak	High risk for DM; lifestyle Adapted Diabetes	**xx**				x			sw

Author/Date	Overall QA[2]	Focus	Wt / BMI	A1C	Lipids LDL-C	SBP / DBP	Baseline LDL-C	Baseline SBP	Disease incidence	Representative[3]
		Prevention Program								
Kramer et al., 2011 [30]	Weak	High risk for DM; lifestyle Adapted Diabetes Prevention Program	**xx**		x	**xx**	3.1	128		sw
Saaristo et al. 2010 [24]	Weak	Prediabetes, lifestyle Finish Diabetes Prevention Program (FIN-D2D)	x		x	x			DM incidence: NGT = 1-2% IFG =7-14% IGT = 11-16% Relative Risk (RR) of DM by weight lost: *≥5% weight loss:* RR, 0.31 (95% CI, 0.16 to 0.59) *2.5-4.9% weight loss:* RR, 0.72 (95% CI, 0.46 to 1.13) *Gained ≥2.5% weight:* RR, 1.10 (95% CI, 0.77 to 1.58)	vl

[1]All studies bolded **xx** demonstrated clinically relevant weight loss (≥3% weight loss OR decrease of ≥1 BMI unit), glycated hemoglobin (A1C) (≥1% decrease), LDL-cholesterol (≥11% decrease in LCL-C levels) and blood pressure [BP] (≥4% decrease in systolic [SBP] or diastolic [DBP]).

[2] QA = quality assessment rating [15].

[3]Representative refers to the question: Are the individuals selected to participate likely to be representative of the target population? vl = very likely; sw = somewhat likely

TC = total cholesterol; med mgt= medical management, MetS = metabolic syndrome, DM = diabetes, NGT = normal glucose tolerance, IFG = impaired fasting glucose, IGT = impaired glucose tolerance

Table 3: Providers and Delivery Channels of Prediabetes or Metabolic Syndrome Studies

	Comparison of Providers						Delivery Channel				
Author / Date	**MD/ RN/ NP only[1]**	**Dietitian included**	**Other allied health**	**Lay person**	**Other Educator**	**Provider Education[2]**	**One- on-one**	**Group**	**Telephone**	**Computer / Internet**	**Mail**
Randomized Controlled Trials											
Bo et al., (2007)[19]		X				X(1)	X	X			
Kulzer et al., (2009)[29]			X					X			
Moore et al., (2011)[28]					X	X(1)	X	X			
Penn et al., (2009) [27]		X					X	X			X
Sakane et al., (2011)[26]	X	X					X	X	X		
Before and after cohort											
Bihan et al. (2009) [55]	X						X		X		
Kramer et al., (2009) [31]		X			X	X (2)		X			
Kramer et al. (2011)[30]		X				X (3)		X			
Saaristo et al., (2010) [24]	X	X					Varied X	X	X		X

[1] MD = physician, RN = registered nurse, NP = nurse practitioner

[2]Describes detail of provider education; where 1 = brief description, 2 = two to three sentence description, 3 = paragraph description

Table 4: Weight Changes in Relevant Prediabetes or Metabolic Syndrome Studies

				INTERVENTION GROUP					NET (Intervention-Control)	
				Baseline			Baseline-Post or F/U			
Author/Date	**Overall QA**	**Intervention Length (mo.)**	**F/U (mo.)**	**N**	**Mean BMI**	**Mean Weight (kg)**	**Δ in BMI**	**% Weight Loss**	**NET Δ BMI**	**NET % WEIGHT LOSS**
Randomized Controlled Trials										
Bo et al., (2007) [19]	Strong	12		169	29.7	81.7	0.3	0.9	0.9	3.2
Kulzer et al., (2009)[29]	Moderate		12	91	31	92.1	1.3	4.1	0.8	2.6
Moore et al. , (2011) [28]	Moderate	6		183	29.7	80.7	0.9	3.2	2.2	1.0
Penn et al., (2009) [27]	Weak	60		51	34.1	93.4		2.5		2.5
Sakane et al., (2011) [26]	Weak	6	36	123	24.8	64.9		2.8		0.6
Cohort – One Group										
Kramer et al. (2009) [31]	Weak	3	12	42	34.6	94.7		4.8		
Kramer et al. (2011) [30]	Weak		12	81	37.1	101.5	1.8	5.0		
Saaristo et al (2010) [24]	Weak		12							
Males				919	30.9	95.8	0.4	1.4		
Females				1879	31.6	83.8	0.4	1.3		

QA = quality assessment rating [15], mo = months, int= intervention, F/U= last follow-up measurement

Table 5: At Risk for Diabetes or Metabolic Syndrome Studies with no Clinically Relevant Changes or Excluded for Selection Bias

Author / Date	Weight /BMI[1]	A1C[1]	Lipids LDL-C[1]	SBP/ DBP[1]	Disease Incidence, risk reversion, CVD risk	Comment
Absetz et al., 2007 [56]	x		x	x		
Almeida et al., 2010 [57]	x					
Avram et al 2011 [58]	x					
Boltri et al., 2007 [59]						No relevant outcomes
Botomino et al., 2008 [60]	x					
Christian et al., 2011[61]	x		x	x		
Kinmonth et al., 2008 [62]	x	x	x	x		
Laaitikainen et al., 2007 [63]	x		x	x		
Makrilakis et al., 2010 [64]	x		x	x		
Mensink et al., 2003 [65]	x	x	x			
Nilsen et al., 2011 [66]	x	x		x		
Oldroyd et al., 2006 [67]	x		x			
Smith-Raye et al., 2009[68]						No relevant outcomes
Wadden et al., 2011[69]	**xx**		x	x		Not representative
Whittemore et al., 2009 [70]			x			
Yamashiro et al., 2010 [71]	B only	x	x	x		

[1] All studies bolded **xx** demonstrated clinically relevant weight loss (≥3% weight loss OR decrease of ≥1 BMI unit); glycated hemoglobin (≥1% decrease in A1C levels); LDL-cholesterol (≥11% decrease in LCL-C levels) and blood pressure [BP] (≥4% decrease in systolic [SBP] or diastolic [DBP]).

Additional files

Additional file 1 - Search Strategy (File name: Additional file 1 - Search Strategy.docx)

Additional file 2 – Abstract and Full Text Screening Tools (File name: Additional file 2 – Abstract and Full Text Screening Tools.docx)

Additional file 3 – Diabetes Studies (File name: Additional file 3 – Diabetes.docx)

Additional file 4 – Mixed Cardiovascular Risk Studies (File name: Additional file 4 – Mixed CVD Risk.docx)

Additional file 5 – Health Promotion or Weight Loss Studies (File name: Additional file 5 – Health

Promotion or Weight Loss.docx)

Additional file 6 – Hypertension Studies (File name: Additional file 6 – Hypertension.docx)

Additional file 7 – Dyslipidemia Studies (File name: Additional file 7 – Dyslipidemia.docx)

Additional file 8 – Pediatrics Studies (File name: Additional file 8 – Pediatrics.docx)

Additional file 9 – Complex Chronic Disease Studies (File name: Additional file 9 – Complex Chronic Disease.docx)

Additional file 10 – Pregnancy Studies (File name: Additional file 10 – Pregnancy.docx)

Additional file 11- Reviewed Studies (File name: Addiltional file 11 – references.docx)

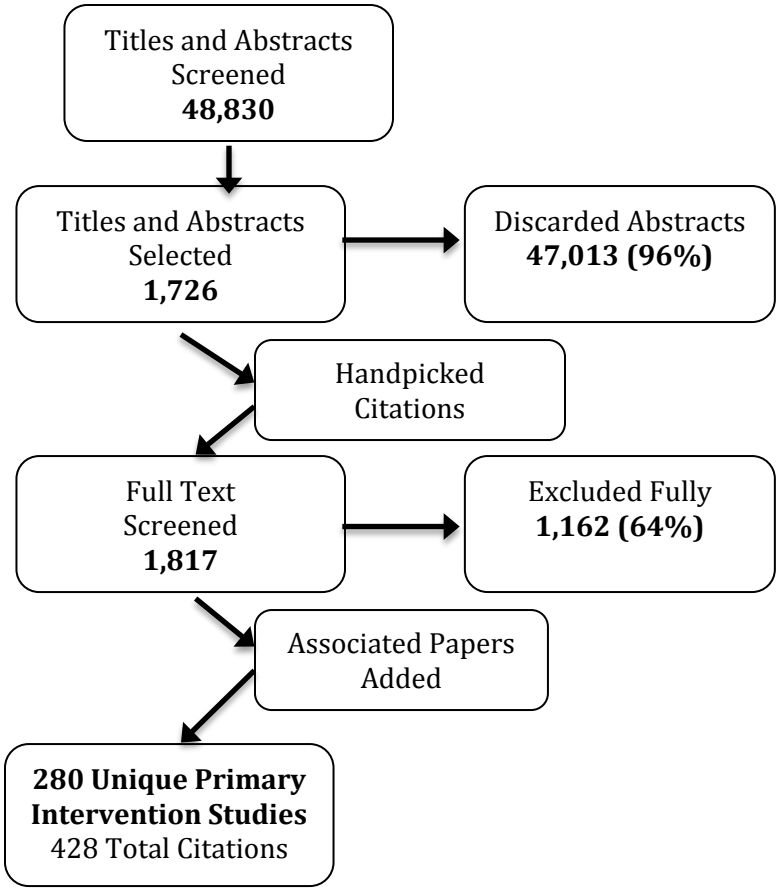
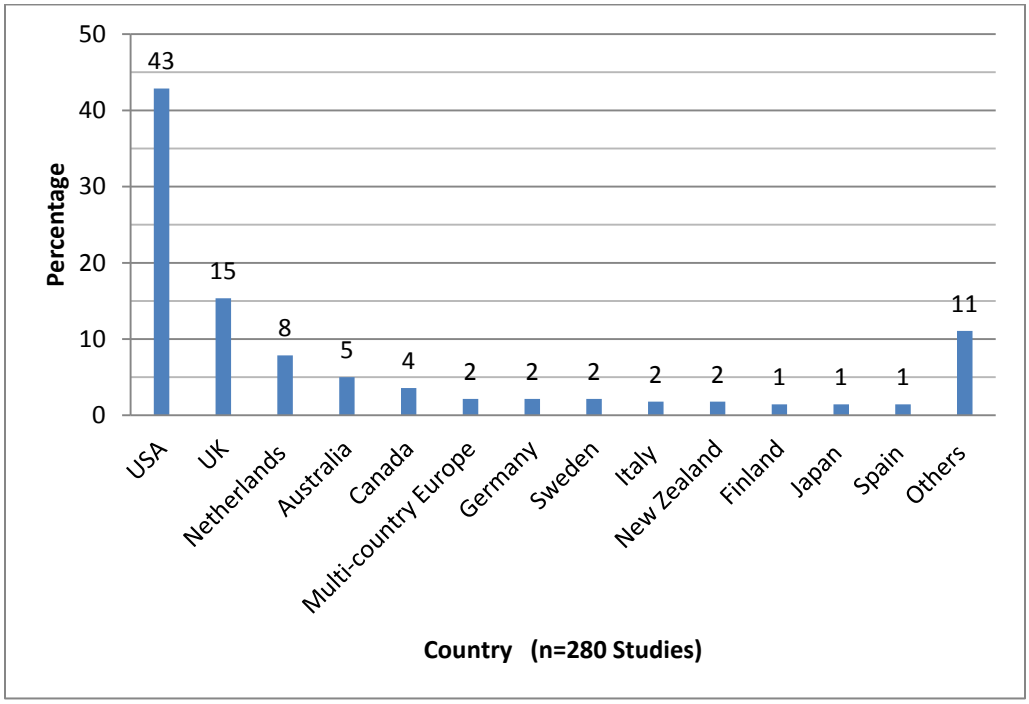


Figure 1. Study Selection Process.

Figure 2. Location of Studies by Country.



Other countries (11% or 31 studies): Denmark 3 studies; France 3; Greece 3; Ireland 3; Norway 3; Belgium 2; Brazil 2; China 2; Switzerland 2; both Australia and New Zealand 1; Austria 1; Chile 1; Korea 1; Mexico 1; Singapore 1; Taiwan 1; Turkey 1.

Figure 3. Number of Studies by Disease/Condition Focus (n=280