The influence of therapeutic alliance on adult obesity interventions in primary care

A systematic review protocol

Elizabeth Sturgiss, Nicholas Elmitt, Jason Agostino, Kirsty Douglas, Alexander M Clark

Background and objectives
Obesity is a common chronic condition, and general practitioners are seeking more effective strategies for assisting their patients. The therapeutic relationship between patients and practitioners is increasingly recognised as a fundamental part of intervention effectiveness. The influence of therapeutic relationships in obesity interventions in primary care has not been systematically studied. We plan to undertake a systematic review and meta-analysis to identify the influence of the therapeutic alliance on the effectiveness of obesity interventions in primary healthcare. The aim of this article is to outline the study protocol.

Methods and analysis
A systematic review of primary care interventions for patients with obesity will be undertaken. Using Bordin's framework for the therapeutic alliance, interventions will be categorised as to whether they incorporate the alliance or not. A meta-analysis will be performed if studies of sufficiently homogenous primary outcome data are found.

Discussion
Understanding the role of the therapeutic alliance on interventions for obesity management will have implications for both future intervention development and the translation of current interventions from trial settings to the real world.

Trial registration: CRD42018091338 in PROSPERO (International prospective register of systematic reviews).

OBESITY IS ONE of the world's most burdensome and escalating population health challenges.[1] More effective strategies for managing patients with obesity are needed within primary care to curb the health burden for communities, the cost implications for health systems and the reduced quality of life for individuals.[2–5] Obesity is defined by a body mass index (BMI) ≥30 kg m^2, with associated health impairments such as impaired glucose metabolism, hypertension, musculoskeletal pain or mental health distress.[6] Current intensive strategies for managing obesity include bariatric surgery, medications and very low energy diets.[7] There is a strong international consensus from the World Health Organization (WHO)[8] and multiple national government and obesity coalitions[7,9–12] that all approaches to obesity management should be underpinned by support for behavioural and lifestyle change, as this increases the effectiveness of all interventions.[13,14]

This review will focus on the behavioural and lifestyle supports that are essential for all approaches to obesity management.

Obesity is a chronic, relapsing, progressive disease that requires costly healthcare over the long term. Primary care is well placed to assist patients with obesity.[2,3,5,12,15,16] Primary care is the first point of contact in a healthcare system. It offers whole-person care (ie care involving any body system); assists patients in a person-centred manner (ie care individualised based on a person's value and beliefs and within the context of their family and community life); and provides continuing care to people over the long term.[17]

As obesity affects many body systems and is a chronic disease, it is essential that primary care services and professionals are supported to manage the condition effectively.[3] Primary care provides the most efficient and cost-effective avenue for chronic disease care within health systems.[17,18]

The relationship between healthcare providers and patients is increasingly being recognised as a key contributor to effectiveness.[19,20] The practitioner–client relationship has been most fully investigated in psychology, with a meta-analysis confirming the strength of the relationship to be moderately associated with outcomes (Spearman's rho = 0.22), which is more than is attributable to any particular form of psychotherapy.[21,22]

The concept of alliance is now well established in the theoretical framework of Bordin[23] from the late 1970s, which extended the concept of the therapeutic relationship from being 'just' about warmth and empathy, to an understanding of the practical and collaborative nature of a helping relationship that he termed the 'Working Alliance'. This three-part model frames the relationship as:

1. 'Bond' – respect, empathy, trust and warmth
2. 'Goals' – collaborative goal setting
3. 'Tasks' – agreed steps to be undertaken to reach the goals.

This model has since been used to develop the Working Alliance Inventory for measuring the practitioner–client alliance in psychology; a high score is associated with better client outcomes.[22,24] Further applications of the tool to other areas of medicine and primary care have also shown the strength of the alliance to be associated with better patient outcomes.[25–27]

With an understanding of the chronic nature of obesity, the importance of supporting primary care and the strength of therapeutic alliances, this systematic review aims to appraise trials of interventions in primary care for obesity management in adults with a focus on the influence of the therapeutic alliance.

The review will answer the following questions:

1. What effect does therapeutic alliance have on the effectiveness of interventions for obesity in adults in primary care?
2. What effect does therapeutic alliance have on the withdrawal rates in obesity management trials in primary care?
3. What effect does therapeutic alliance have on the rates of loss to follow-up in obesity management trials in primary care?

Methods and analysis

A systematic review incorporating a meta-analysis will be used. The review will be prospectively registered in PROSPERO using the PRISMA-P format. We will search MEDLINE, EMBASE, PsycINFO, CINAHL, Cochrane Central Register of Controlled Trials (CENTRAL) and Scopus for original literature and citations. Authors of unpublished trials that are registered with the WHO International Clinical Trials Registry Platform will be contacted up to three times by email for information on their trials. Theses published on Open Access Theses and Dissertations and Networked Digital Library of Theses and Dissertations will be included.

Search strategy

The search strategy is based around the terms 'obesity', 'primary care' and 'intervention'. The Ovid string is detailed in Box 1. This search strategy will be modified where necessary for the other databases. The search strategy has been assessed by a specialist primary care librarian.

Types of study to be included

Controlled trials of interventions (randomised controlled trials [RCTs], cluster RCTs).

Participants and population

To be included in the review, studies must:

- include an adult sample (aged ≥18 years) with confirmed obesity, where obesity is defined as either a BMI of >30 kg/m^2, or by the diagnosis of obesity as defined by the intervention if different. Studies that focus primarily on other chronic conditions or with a purpose of general improvement in nutrition or physical activity will be excluded.
- be published as full papers or theses in English between 1 January 1998 and March 2018.

Intervention

Interventions will include those delivered in primary care and aimed at optimising the health, and/or reducing the body weight, of adults living with obesity. 'Primary care' is defined as the first point of contact in a community-based system. Interventions may be delivered by a single health professional or by a multidisciplinary team of health professionals. Any intervention that occurs for screening or diagnostic purposes will be excluded.

Comparator

The comparator will be guided by the primary studies and classified as either a control (conventional health care) or alternative intervention (variation on the intervention). Pooling will be done according to homogeneity of the interventions.

Box 1. Search strategy for OVID

Obesity

(from US National Library of Medicine www.ncbi.nlm.nih.gov/pubmedhealth/PMH0078945)

1. exp *obesity/
2. exp *overweight/
3. *weight loss/
4. exp *weight reduction programs/
5. (obesity or obese).ti.
6. (weight adj2 (los* or reduc*)).ti,ab.
7. (overweight or over-weight or over weight or overeating or over eating or over-eating).ti.
8. or/1–7

AND

Primary care

1. Physicians, Family OR registrar*OR
2. "Family Practice" OR
3. (primary AND health AND care) OR
4. "Primary Health Care" OR
5. (family AND doct*) OR
6. GP OR
7. (general AND pract*) OR
8. (family AND pract*) OR
9. "General Practice"

AND

Intervention

(search strategy from Karen A Robinson, Kay Dickersin; Development of a highly sensitive search strategy for the retrieval of reports of controlled trials using PubMed, International Journal of Epidemiology, Volume 31, Issue 1, 1 February 2002, Pages 150–153, https://doi.org/10.1093/ije/31.1.150)

1. Randomized controlled trial.pt.
2. Controlled clinical trial.pt.
3. Randomized controlled trials/
4. Random allocation/
5. Double-blind method/
6. Single-blind method/
7. Or/1–6
8. Animal/not human
9. 7 not 8
10. Clinical trial.pt.
11. Explode clinical trials/
12. (clinic$ adj25 trial$)tw.
13. ((singl$ or doubl$ or trebl$ tripl$) adj (mask$ or blind$)).tw.
14. Placebos/
15. Placebo$.tw.
16. Random$.tw.
17. Research design/
18. (latin adj square).tw.
19. Or/10–18
20. 19 not 8
21. 20 not 9
22. Comparative study/
23. Explode Evaluations studies/
24. Follow-up studies/
25. Prospective studies/

Limited to adults, Limited to English language, Limited to 1998–2018

Primary outcome(s)

The primary outcome wil be a reduction in body weight or BMI.

Timing and effect measures

We will synthesise outcomes of studies using a random-effects model at similar time points for the data that are available (eg at six months and/or two years). Length of follow-up will not be used as an exclusion criterion.

While we acknowledge that long-term weight reduction is much more problematic in obesity than short-term weight loss, this systematic review aims to investigate the effectiveness of the therapeutic alliance in existing obesity studies.

Secondary outcome(s)

Secondary outcomes include:

- loss to follow-up
- withdrawal of participants
- quality-of-life measures
- metabolic risk outcomes (hypertension, blood glucose levels, lipids).

All secondary outcome measures included in trials will be collected.

Timing and effect measures

Outcomes will be measured and/or assessed over a specified period, depending on the data presented in the studies. Length of follow-up will not be used as an exclusion criterion; however, proportion of participants lost to follow-up will be examined.

Data extraction (selection and coding)

Two reviewers will screen all titles and abstracts independently using Covidence software on the basis of the headings detailed above.

Conflicts will be resolved by discussion, with studies retained for full text screening if agreement is not reached. Where there is ambiguity, abstracts will be retained for full text assessment. Where no abstract is available, records will be retained for full text assessment unless they can be judged from the title not to relate to the review topic.

Full text screening

Two reviewers will assess full texts of all potentially eligible studies using a piloted checklist. Disagreement about eligibility will be resolved by discussion, involving a third reviewer where necessary.

Data extraction

Two reviewers will independently extract data using piloted data extraction forms (Box 2). Data extracted will be categorical or continuous. Qualitative extraction will be avoided, if possible, to aid with pooling of the data.

The presence or absence of therapeutic alliance within the intervention will be defined on the basis of the Bordin framework for working alliance:

1. the **bond** between the two parties:
   a. is there a pre-existing relationship with the provider of the intervention? (Yes/No)
      OR
   b. will there be an ongoing relationship with the provider of the intervention after the trial? (Yes/No)
2. collaborative **goal** setting: did the intervention involve collaborative goal setting? (Yes/No)
3. agreement on the required **tasks** to reach the goals: did the intervention involve agreement on the tasks to be undertaken (eg not protocol driven, room for individualisation for the patient)? (Yes/No)

Three subgroups for the therapeutic alliance will be defined as:

- Group 1 – none of the above components and constitutes 'general education'
- Group 2 – one or two components (ie bond plus either tasks or goals)
- Group 3 – all three components, and/or the intervention specifically measured therapeutic alliance (although must not have 'bond' as the only component described).

Where studies of relevant interventions are identified but data relating to therapeutic alliance is not reported separately, authors of included papers will be contacted by email to attempt to obtain this data.

Risk of bias (quality) assessment

The quality of included studies will be assessed independently by two reviewers using the risk of bias criteria detailed in Cochrane Collaboration Risk of Bias Tool.[28] Risk of bias relating to the primary outcome will be assessed and presented for each study in a risk of bias table.

Strategy for data synthesis

A meta-analysis will be performed if studies of sufficiently homogenous primary outcome data are found. Homogeneity will be determined statistically via I^2, as well as descriptively focusing on methodological and clinical variation. Change from baseline data or endpoint date will be used. For variables with the same scale, weighted mean difference with 95% confidence intervals (CI) will be used; for those with a different scale, standardised mean difference with 95% CI will be calculated. All pooling of data will use the DerSimonian and Laird random effects model. This reflects the diverse and complex nature

Box 2. Data to be included in the data extraction template

- Population studied, definition of obesity used
- Demographics and baseline characteristics
- Details of the intervention, including:
  - health professional(s) involved
  - aim of intervention
  - health-service context
  - specific training involved
  - mode of delivery
  - description of intervention (components thereof)
  - frequency, duration, and intensity of delivery
  - any theoretical model used to underpin or evaluate the intervention
- Study method/trial design
- Details of the control/comparison intervention (include any detail of what characterises 'usual care' in the setting under investigation)
- Indicators of acceptability to users
- Methods of recruitment and retention
- Outcomes reported, including definitions and measures used to quantify
- Impact of intervention on primary and secondary outcomes (report 95% confidence intervals for all quantitative outcomes)
- Suggested mechanisms of intervention action

of the interventions included. Statistical heterogeneity will be measured using I^2 statistics and classified as negligible ($I^2 = 0\%$), minimal ($I^2 < 20\%$), moderate ($20\% < I^2 < 50\%$) or substantial ($I^2 < 50\%$). In instances in which studies are too heterogeneous to combine quantitatively, a narrative synthesis will be done.

Analysis of subgroups

1. Therapeutic alliance presence
   - Group 1 – will have none of the above components and will represent general education
   - Group 2 – will have one to two components (ie bond plus either tasks or goals)
   - Group 3 – will have all three, and/or the intervention specifically measured therapeutic alliance (although must not have 'bond' as the only part they describe)
2. Time-intensiveness – both as per protocol and what actually eventuated in the trial
   - Group 1 – one consultation
   - Group 2 – two to five consultations
   - Groups 3 – more than five consultations
3. Was the intervention delivered in regular practice?
4. Did usual provider refer to the intervention?

Discussion

This systematic review and meta-analysis will provide new and important knowledge of how and why obesity interventions in primary care might work. To improve the effectiveness of interventions in primary care, unpacking the how and why interventions work is important. The information from this systematic review will be used to inform future intervention development, translation of intervention trials into clinical practice and assessment of interventions for effectiveness.

This systematic review may have wider applications outside the field of obesity. The findings may be important for primary care interventions in general.

Authors

Elizabeth Sturgiss FRACGP, FHEA, BMed, MPH, MForensMed, Lecturer, Academic Unit of General Practice, Australian National University Medical School, Australian National University, Canberra Hospital Campus, ACT. Elizabeth.sturgiss@anu.edu.au

Nicholas Elmitt BA(Hons), MCHaM, Senior Research Officer, Academic Unit of General Practice, Australian National University Medical School, Australian National University, ACT

Jason Agostino FRACGP, MAppEpid, BMed, DCH, Lecturer, Academic Unit of General Practice, Australian National University Medical School, Australian National University, ACT

Kirsty Douglas MBBS, Dip RACOG, MD, FRACGP, Professor of General Practice, Academic Unit of General Practice, Australian National University Medical School, Australian National University, ACT

Alexander M Clark PhD RN, BA(Hons) FCAHS, Professor & Associate Vice President (Research), University of Alberta, Canada

Competing interests: None.

Provenance and peer review: Not commissioned, externally peer reviewed.

Acknowledgements

With thanks to Tony Parsons, Librarian at The Royal Australian College of General Practice John Murtagh Library for his assistance in reviewing the search strategy.

References

1. World Health Organization (WHO). Global Action Plan for the prevention and control of noncommunicable diseases 2013–2020. Geneva: WHO, 2013.
2. Asselin J, Osunlana AM, Ogunleye AA, Sharma AM, Campbell-Scherer D. Missing an opportunity: The embedded nature of weight management in primary care. Clin Obes 2015;5(6):325–32. doi: 10.1111/cob.12115.
3. Jansen S, Desbrow B, Ball L. Obesity management by general practitioners: The unavoidable necessity. Aust J Prim Health 2015;21(4):366–68.
4. Swinburn B, Arroll B. Rethinking primary care systems for obesity. Lancet 2016;388(10059):2452–54. doi: 10.1016/S0140-6736(16)31913-4.
5. Bennett WL, Wang NY, Gudzune KA, et al. Satisfaction with primary care provider involvement is associated with greater weight loss: Results from the practice-based POWER trial. Patient Educ Couns 2015;98(9):1099–105. doi: 10.1016/j.pec.2015.05.006.
6. Sharma AM, Campbell-Scherer DL. Redefining obesity: Beyond the numbers. Obesity (Silver Spring) 2017;25(4):660–61. doi: 10.1002/oby.21801.
7. National Health and Medical Research Council (NHMRC). Clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children in Australia (2013). Melbourne: NHMRC, 2013.
8. World Health Organization (WHO). Obesity: Preventing and managing the global epidemic. Geneva: WHO, 2000.
9. National Clinical Guideline Centre (UK). Obesity: Identification, assessment and management of overweight and obesity in children, young people and adults: Partial update of CG43. London: National Institute for Health and Care Excellence (UK), 2014.
10. Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity. Endocr Pract 2016;22 Suppl 3:1–203. doi: 10.4158/EP161365.GL.
11. Lau DC, Douketis JD, Morrison KM, et al. 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults and children [summary]. CMAJ 2007;176(8):S1–13.
12. New Zealand Ministry of Health. Clinical guidelines for weight management in New Zealand adults. Wellington: New Zealand Ministry of Health, 2017.
13. Kushner RF, Ryan DH. Assessment and lifestyle management of patients with obesity: Clinical recommendations from systematic reviews. JAMA 2014;312(9):943–52. doi: 10.1001/jama.2014.10432.
14. McGrice M, Don Paul K. Interventions to improve long-term weight loss in patients following bariatric surgery: Challenges and solutions. Diabetes Metab Syndr Obes 2015;8:263–74. doi: 10.2147/DMSO.S57054.
15. Campbell-Scherer D, Sharma AM. Improving obesity prevention and management in primary care in Canada. Curr Obes Rep 2016;5(3):327–32. doi: 10.1007/s13679-016-0222-y.
16. Sturgiss EA, van Weel C, Ball L, Jansen S, Douglas K. Obesity management in Australian primary care: Where has the general practitioner gone? Aust J Prim Health 2016;22(6):473–76. doi: 10.1071/PY16074.
17. Starfield B, Shi L, Macinko J. Contribution of primary care to health systems and health. Milbank Q 2005;83(3):457–502.
18. Hansen J, Groenewegen PP, Boerma WG, Kringos DS. Living in a country with a strong primary care system is beneficial to people with chronic conditions. Health Aff (Milwood) 2015;34(9):1531–37. doi: 10.1377/hlthaff.2015.0582.
19. Kelley JM, Kraft-Todd G, Schapira L, Kossowsky J, Riess H. The influence of the patient-clinician relationship on healthcare outcomes: A systematic review and meta-analysis of randomized controlled trials. PloS One 2014;9(4):e94207. doi: 10.1371/journal.pone.0094207.
20. Melendez-Torres GJ, Sutcliffe K, Burchett HED, Rees R, Richardson M, Thomas J. Weight management programmes: Re-analysis of a systematic review to identify pathways to effectiveness. Health Expect 2018;21(3):574–84. doi: 10.1111/hex.12667.
21. Martin DJ, Garske JP, Davis MK. Relation of the therapeutic alliance with outcome and other variables: A meta-analytic review. J Consult Clin Psychol 2000;68(3):438–50.
22. Elvins R, Green J. The conceptualization and measurement of therapeutic alliance: An empirical review. Clin Psychol Rev 2008;28(7):1167–87. doi: 10.1016/j.cpr.2008.04.002.
23. Bordin ES. The generalizability of the psychoanalytic concept of the working alliance. Psychother Theory, Research & Pract 1979;16(3):252–60.
24. Horvath AO, Symonds BD. Relation between working alliance and outcome in psychotherapy: A meta-analysis. J Counsel Psychol 1991;38(2):139–49.
25. Fuertes JN, Mislowack A, Bennett J, et al. The physician-patient working alliance. Patient Educ Couns 2007;66(1):29–36.
26. Sturgiss EA, Sargent GM, Haesler E, Rieger E, Douglas K. Therapeutic alliance and obesity management in primary care – A cross-sectional pilot using the Working Alliance Inventory. Clin Obes 2016;6(6):376–79. doi: 10.1111/cob.12167.
27. Chan A. The working alliance as a conceptual framework of patient-centredness: The development of the primary care Working Alliance Inventory. London: University of Western Ontario, 2008.
28. Higgins JPT, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011;343:d5928. doi: 10.1136/bmj.d5928.