REVIEW: TYPE 2 DIABETES AND PHYSICAL ACTIVITY INTERVENTIONS IN CLINICAL SETTINGS -- ABSTRACTION FORM, Version 7

REVIEWER NAME: _____ **DATE:** _____

Main Article PubMed ID: _____

Title: _____

Lead Author _____

Topic Area (check all that apply):

☐ Diet and nutrition ☐ Medication adherence

☐ Physical activity ☐ Smoking

☐ other, please specify: _____

Intervention Modality (check all that apply):

☐ Non-tailored behavioral intervention (e.g. simple exercise prescription) ☐ Tailored behavioral intervention

☐ In-person counseling ☐ Phone counseling ☐ Interactive voice response ☐ Printed materials ☐ Text

☐ Web-based ☐ Video/DVD ☐ Exercise prescription ☐ Family-based

☐ Other, please specify: _____

Setting:

☐ Healthcare

☐ Healthcare + other - please specify: _____

Study Design:

☐ RCT ☐ Other, please specify: _____

Target Audience:

☐ Type 2 Diabetes

Instructions:

1) Read "The PRECIS-2 tool: designing trials that are fit for purpose" by Loudon, et al (2015), and use it for reference while rating articles.
2) Have PRECIS2 table in front of you, and use the PRECIS-2 website as a guide (https://crs.dundee.ac.uk/precis):
   5 = Completely pragmatic 1 = Completely explanatory
3) Do not rate any feasibility studies or pilot studies (please notify [LEAD AUTHOR] if you were assigned a feasibility/pilot study to review)
4) Rate each question separately
5) Rate only on items reported in the study; please do not assume

6) Use ”NA” rating *only* when truly necessary, meaning truly “not applicable” (i.e. web-only intervention, no staff necessary)
7) If multi-component intervention, rate conservatively (i.e. towards explanatory), focusing on physical activity component
8) If study design has multiple arms, rate only the physical activity arm as treatment arm
9) If study design has multiple arms with more than one physical activity arm, then rate the more complex physical activity arm as treatment arm and least complex as control and;
10) Use Comment section for any issues, concerns, or items worth highlighting

1. **Eligibility Criteria** (exclusions, only include motivated) – the extent to which participants in the trial are similar to those who would potentially receive the intervention in the usual care setting

EXAMPLE: Early treatment with prednisolone or acyclovir in Bell’s Palsy (Sullivan FM, Swan IR, Donnan PT, et al., 2009)

- Inclusion criteria – Patients with confirmed diagnosis: ≥ 16 years of age with unilateral facial nerve weakness of no identifiable cause who presented to primary care or an emergency department and could be referred to a collaborating otorhinolaryngologist <72 hours after the onset of symptoms.
- Exclusion criteria – Pregnancy, breast feeding, uncontrolled diabetes, peptic ulcer disease, suppurative otitis media, herpes zoster, multiple sclerosis, systematic infection, sarcoidosis and other rare conditions, and an inability to provide informed consent.
- Extra test – Randomised controlled trial of Bell’s palsy treatment requited senior otorhinolaryngologist in hospitals to confirm a patient’s eligibility to participate. Bell’s palsy is usually diagnosed by a general practitioner in primary care.
- Suggested PRECIS score – 2, rather explanatory

5	4	3	2	1
Completely Pragmatic				Completely Explanatory
→No exclusions. →Selection criteria highly inclusive →Systematic effort made to recruit sample representative of population setting expected to receive intervention in usual care setting		→Some exclusions →Selection criteria limit study population to an extent →Most “typical” participants included		→Stepwise selection criteria. →Restricted to participants highly responsive to experimental intervention. →Sample much more narrow than expected representative population.
Comments:				

2. **Recruitment Path** (effort made to recruit participants) – how much extra effort is made to recruit participants over and above what would be used in the usual care setting to engage with patients

EXAMPLE: Leukotriene antagonists for asthma treatment (Price D, Musgrave SD, Shepstone L, et al., 2011)

- Initially extra resources were used to recruit patients at 53 primary care practices. Patients were recruited via a postal questionnaire to identify symptoms and trial eligibility, not just to invite to participate. This would push the recruitment path of this domain towards the explanatory end. By using this method of recruitment, which requires administration not normally present in primary care, it is possible that responders may be healthier than those at the clinic being invited to the trial and also more highly motivate and compliant as they have come through a different route than those invited during a clinic attendance.
- In this trial, recruitment was inadequate using a postal questionnaire, so participants were then recruited through clinic attendances changing the recruitment towards a more pragmatic trial design, creating results which are more applicable to users of the results in a primary care setting.
- Suggested PRECIS score – 2, rather explanatory; but, as trial continued, a PRECIS score of 3 (equally pragmatic and explanatory) since trial now more a mix of recruitment methods, some of which are feasible in usual care.

5	4	3	2	1
Completely Pragmatic				Completely Explanatory
→Participants recruited unobtrusively during clinic visits or through standard patient outreach (e.g., use typical usual care processes of outreach: letters, automated calls or emails generated by EMR)		→Some extra effort and/or resources used, above and beyond what would be used to recruit participants in usual PCMH care (e.g., staff time needed to contact people from EMR search)		→General advertising without relevance to clinic population** →Recruitment requiring extra effort →High level of incentive offered
Comments: **SHOULD BE EXCLUDED FROM ANALYSIS IF THIS IS PRESENT				

3. **Setting** (how different are settings of trial from usual care?) – the difference in the settings of the trial from the usual care setting where the results are likely to be applied

EXAMPLE: Manual physical therapy versus corticosteroid injection to treat shoulder impingement (Rhon DI, Boyles RE, Cleland JA, et al., 2011)

- Single centre and specialised centre (Madigan Army Medical Center, USA), unlikely to be the usual setting for most individuals receiving physiotherapy for shoulder impingement.
- Suggested PRECIS score – 2, rather explanatory, dependent on how different raters think the treatment centre is similar from usual setting in the country they live in.

5	4	3	2	1
Completely Pragmatic				Completely Explanatory
→Setting nearly identical to location where results are intended to be applied (usual care) →Multiple centers selected for variation		→Setting is partially representative of usual care sites →More than one center involved		→Study not at all representative of usual care site (i.e., highly specialized centers or tertiary-care academic centers) →Few or one clinical center involved
Comments:				

4. **Organization** (resources, provider expertise, and organization of care delivery) – the difference between the resources, provider expertise, and the organization of care delivery employed in the intervention arm of the trial and those available in usual care

EXAMPLE: Establishment of Acute Respiratory Distress Syndrome (ARDS) Network in 1994 (NEJM, 2000)

- Multicenter clinical trials of ARDS treatments, but there was difficulty translating results from a trial involving low tidal volume (Vt) into usual clinical practice
- Ten academic centers with 75 intensive care units
- Extra staff, and very labor intensive
- Used additional equipment beyond usual care, none of which was planned for at the trial design stage
- Suggested PRECIS score – 1, very explanatory

5	4	3	2	1
Completely Pragmatic				Completely Explanatory
→Intervention integrated into structure of usual care setting. →No extra staff time or resources required beyond what would be expected in usual care (patient-centered medical home). →Staff require no or minimal additional training beyond what is expected in the usual care setting		→Intervention requires some extra staff time and additional infrastructure. →Requires moderate additional training for intervention delivery or modest additional practitioner experience beyond what is expected in usual care (e.g., extra years in practice, 1-2 days of special training).		→Intervention requires many extra hours of staff time and additional infrastructure. →Requires additional highly specialized staff and/or significant extra training, beyond what is seen in usual care setting.
Comments:				

5. **Flexibility (delivery by intervention staff)** – the difference in flexibility of intervention delivery compared to the flexibility anticipated in usual care

EXAMPLE: Elective caesarean section syntocinon infusion trial (Murphy DJ, Carey M, Montgomery AA, et al., 2009)

- Protocol drive – Much detail give, with protocol violations recorded in self reported case form. Investigators accept this may occur due to clinical needs (such as anaesthesia).
- Co-interventions – Specific direction
- Complications – Specific directions for managing complications or side effects
- Improving adherence – No measures in place
- Suggested PRECIS score – 2, rather explanatory

NA	5	4	3	2	1
	Completely Pragmatic				Completely Explanatory
	→No extra measures employed to increase practitioner adherence (but OK to just monitor practitioner delivery). →Program outline/M.O.P. may be provided, but the specifics of intervention delivery (e.g., dose schedule, description of educational program) are left to interpretation by practitioner.		→Some strategies to monitor and increase practitioner adherence. →Intervention delivery somewhat pre-specified but with some flexibility (e.g., dose schedule, description of educational program left to discretion of practitioner).		→Extensive actions made to enhance provider adherence attention to details. →Intervention highly specified and protocol-driven (e.g., Highly specific Manual of Procedures (M.O.P.) in place)
Comments:					

6. **Flexibility (adherence)** – the difference in the flexibility in how participants engage with the intervention compared to the flexibility anticipated in usual care

EXAMPLE: Music therapy to support communication in autistic children (Geretsegger M, Holck U, Gold C., 2012)

- The sessions were all individual based on interaction with child and allowed for range of responses to the intervention
- Suggested PRECIS score – 5, very pragmatic

5	4	3	2	1
Completely Pragmatic				Completely Explanatory
→No measurement of participant adherence to intervention →No strategies to increase participant adherence →Encouragement to comply with intervention is acceptable (only if within the realm of what would be seen in usual care) →Requiring face-to-face meetings/study visits prior to randomization is acceptable unless the INTENT was to exclude non-compliant participants		→A few strategies to measure and increase participant adherence		→Close monitoring →Actions to maximize participant adherence →Participants intentionally excluded if unlikely to be adherent (e.g., behavioral run-in phase where physical activity tracking required to go on in trial)
Comments:				

7. **Follow-up** (how closely are patients followed up) – the difference in the intensity of follow-up of participants (including data requiring interaction) during the trial compared to the typical follow-up expected in usual care

EXAMPLE: Perioperative β blockade for patients undergoing infra-renal vascular surgery (Brady AR, Gibbs JSR, Greenhalgh RM, et al., 2005)

- Clinical follow-up until patient left hospital (discharge or death) or until 30 days after surgery, whichever was the longer, so more than usual care.
- Monitoring intensity involved more extensive data collection than usual:
    - Pre-operation – three-lead electrocardiogram (ECG) Holter monitor (Flashcard with 2x48 hour recording) set up on each patient and maintained for 72 hours.
    - Troponin values at 1, 3, and 7 days after surgery (more usual for only 1 and 3 days after surgery)
    - ECG after randomization and at 7 and 30 days after surgery.
- Unscheduled follow-up visits triggered by primary outcome a cardiovascular event (such as angina, myocardial infarction, stroke)
- Suggested PRECIS score – 1, very explanatory

5	4	3	2	1
Completely Pragmatic				Completely Explanatory
→No (or minimal) additional visits of study individuals during intervention phase where may influence efficacy →Ok if extensive data collected, as long as it is *after* intervention →No or infrequent follow-up by practitioner		→Some added visits during intervention phase →Some data collected during intervention (but not much beyond what would be expected in usual care) →Occasional practitioner follow-up		→Much more frequent visits for data collection **during** intervention period. →Extensive data collected ***during*** intervention. →Frequent practitioner follow-up
Comments:				

8. **Primary Outcome** (how clinically meaningful and understandable is the PRIMARY OUTCOME to patients, healthcare providers, society, and policy makers; outcome could practically be assessed with resources available in usual care setting) – the extent to which the trial's primary outcome is directly relevant to participants and other stakeholders.

EXAMPLE: Early treatment with prednisolone or acyclovir in Bell's palsy (Sullivan FM, Swan IR, Donnan PT, et al., 2009)

- Primary outcome – Recovery of facial function as rated on the House-Brackmann scale.
- Test not routinely used in primary care and requires training. It is, however, an easy clinical test widely used in secondary care for grading recovery from facial nerve paralysis caused by damage to lower motor neurons.
- Central adjudication – Photographs taken of patients were assessed and graded independently by a panel of three experts (not general practitioners, who usually assess).
- Suggested PRECIS score – 1, very explanatory

5	4	3	2	1
Completely Pragmatic				Completely Explanatory
→Primary outcome is relevant, understandable and important to patients' diabetes management as well as to society, policy-makers and healthcare providers →Could be assessed with resources available in in usual care setting		→Clinical measures that are somewhat relevant and understandable to patients, society, policy-makers and healthcare providers →Could be assessed in usual care with some additional training/expertise		→Only uses biomarkers or measures/terms that are not relatable to patients, society, policy-makers and healthcare providers. →Requires specialized training to collect and not feasible to measure in usual care.
Comments:				

9. **Analysis** (Intention-to-Treat; vs. supplemented by per protocol) – the extent to which all data is included in analysis of the primary outcomes

EXAMPLE: Effects of Rosuvastatin versus atorvastatin on LDL and HDL cholesterol in patients with type IIa or IIb hypercholesterolemia (Davidson M, Ma P, Stein EA, et al., 2002)

- Dietary lead in to screen and exclude non-compliers, then post-randomization excluded non-compliers who did not take medication, so "per protocol analysis." The trial did, however, include those who violated protocol, deviated from protocol, or withdrew (mainly due to adverse events)
- Suggested PRECIS score – 2, rather explanatory

5	4	3	2	1
Completely Pragmatic				Completely Explanatory
→ITT (all participants) under usual conditions, with multiple imputation of missing data →No exclusion of data from non-compliant participants from analysis →No exclusion of data from trial sites with lower than expected recruitment →Various missing data analytic procedures are OK as long as not excluding due to poor adherence		→ITT is primary analysis but analysis rigor reduced slightly in some way →Various missing data analytic procedures are OK as long as not excluding due to poor adherence		→Rather than ITT, uses a type of "as treated" analysis →Data analyzed excludes individuals who violated/deviated from protocol ("per protocol analysis"), →Excludes data from trial sites or providers who recruited below expectations or had poor adherence →Various missing data analytic procedures are OK as long as not excluding due to poor adherence
Comments:				

Other External Validity Factors related to RE-AIM

(Use same training and scoring steps as for main 10 PRECIS-2 ratings)

10. Participant Engagement (the extent to which participants' used all parts of the physical activity intervention, including services/materials)

5	4	3	2	1	
Completely Pragmatic				Completely Explanatory	
→Reported and participants actively engaged in intervention →High level of use of services, materials		→Reported and participants periodically engaged in intervention →Some use of services, materials		→No mention of participants' level of engagement/interaction with intervention (reporting attrition rate does not qualify as engagement) →Extremely low usage of service materials A) Mentioned in article B) Not mentioned in article	
Comments:					

11. Adaptation/Change (extent of intervention modifications; corrections during study)

5	4	3	2	1	
Completely Pragmatic				Completely Explanatory	
→Detailed reporting on modifications made and rationale →Use of QI procedures →Responsive to site feedback		→Reporting of some changes to intervention or measures in response to feedback		→No mention of modifications to protocol for recruitment, intervention or measures →Very few intervention modifications or corrections made during study A) Mentioned in article B) Not mentioned in article	
Comments:					

12. Program Sustainability (extent of efforts to continue behavioral intervention after study)

5	4	3	2	1	
Completely Pragmatic				Completely Explanatory	
→Detailed reporting of intervention sustainability →Explicit plans for handling off intervention site		→Some discussion of modest efforts to sustain intervention at study end		→No report of efforts to continue intervention after study A) Mentioned in article B) Not mentioned in article	
Comments:					

13. Unintended Effects (extent to which harmful or beneficial consequences were reported)

5	4	3	2	1	
Completely Pragmatic				Completely Explanatory	
→Explicit discussion of efforts to prevent harm to participants, report on or capture unintended benefits above and beyond IRB requirements		→Some discussion of efforts to prevent harm to participants or capture unintended benefits additional to IRB requirements		→No efforts to prevent or report harm to participants or capture unintended benefits only necessary for IRB requirements A) Mentioned in article B) Not mentioned in article	
Comments:					

14. **Monetary Costs of Existing Treatment** (extent to which costs of the physical activity intervention are costly for a patient-centered medical home type of clinic)

5	4	3	2	1	
Completely Pragmatic				Completely Explanatory	
→Explicit discussion costs →Low cost →Explicit efforts to constrain costs →Minimal extra interaction with low cost provider (medical assistant or peer counselor) and/or low # visits (1-2 over 6 months) additional than usual care		→Some discussion cost; moderate replication costs →Some extra interaction with moderate cost provider (RN, MSW) and/or moderate # visits (3-4 over 6 months) additional than usual care		→No reported costs →Very high costs →Extra interaction with high-cost provider (MD, PhD) and/or high # visits than usual care ≥5 over 6 months) A) Mentioned in article B) Not mentioned in article	
Comments:					

General Comments: