Appendix 2: Examples of various formats which can be used by authors to describe and/or provide exercise intervention materials

1. DEDICATED TRIAL WEBSITES

PACE RCT

White PD, Goldsmith KA, Johnson AL, Potts L, Walwyn R, DeCesare JC, et al. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. Lancet 2011; 377: 823-36.

<u>www.pacetrial.org</u> – this trial website contains trial information, including the treatment and training manuals, participant newsletters.

 Promoting Wellbeing for Women With Depression: A Pragmatic Randomised Controlled Trial (RCT) of an Exercise Programme

Callaghan P, Khalil E, Morres I, Carter T. Pragmatic randomised controlled trial of preferred intensity exercise in women living with depression. BMC Public Health. 2011. 12;11: 465. doi: 10.1186/1471-2458-11-465.

http://www.nottingham.ac.uk/nursing/exercise_wellbeing/index.php - the trial website provides information about the project, the research term, the results and a full report

2. JOVE (Journal of Visualised Experiments) www.jove.com

The *Journal of Visualized Experiments* (styled *JoVE*) is a peer-reviewed scientific journal that publishes experimental methods in video format. Videos in the *Journal of Visualized Experiments* make it easier for a second researcher to follow the same procedures as the original researcher.

• Keller J L, Fritz N, Chiang CC, Jiang A, Thompson T, Cornet N, *et al.* Adapted Resistance Training Improves Strength in Eight Weeks in Individuals with Multiple Sclerosis . J Vis Exp. 2016; (107): e53449, doi: 10.3791/53449.

Hip weakness is a common symptom affecting walking ability in people with multiple sclerosis. Isolated muscle strengthening is a useful method to target specific weaknesses. This protocol describes a progressive resistance-training program using exercise bands to increase hip muscle strength.

 Rizk, A K, Wardini R, Chan-Thim, E., Trutschnigg, B., Forget, A., Pepin, V. Using Continuous Data Tracking Technology to Study Exercise Adherence in Pulmonary Rehabilitation. J Vis Exp. 2013; (81): e50643, doi: 10.3791/50643.

Pulmonary rehabilitation is widely recognized in the management of respiratory diseases. A key component to successful pulmonary rehabilitation is adherence to the recommended exercise training. The purpose of the present protocol is to describe how continuous data tracking technology can be used to precisely measure adherence to a prescribed aerobic exercise program.

Hunt, M. A. Movement Retraining using Real-time Feedback of Performance. J Vis Exp. 2013;
 (71), e50182, doi: 10.3791/50182.

Retraining abnormal movement patterns following injury or disease is a key component of physical rehabilitation. Recent advances in technology have permitted accurate assessment of movement during a variety of tasks, with near instantaneous quantification of results. This provides new opportunities for modification of faulty movement patterns in real time.



3. ONLINE APPENDIX – SUPPLEMENTARY DATA

 White PD, Goldsmith KA, Johnson AL, Potts L, Walwyn R, DeCesare JC, et al. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. Lancet 2011; 377: 823-36.

This publication provides an online appendix with photos and detailed descriptions

http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(11)60096-2/supplemental

4. ONLINE VIDEO- SUPPLEMENTARY DATA

Anding K, Bar T, Trojniak-Hennig J, Kuchinke S, Krause R, Rost JM, Halle M. A structured exercise programme during haemodialysis for patients with chronic kidney disease: clinical benefit and long-term adherence. BMJ Open. 2015; 5:8 e008709 doi:10.1136/bmjopen-2015-008709

Supplementary Data: This web only file has been produced by the BMJ Publishing Group from an electronic file supplied by the author(s) and has not been edited for content.

Data supplement 2 - Online video 1: http://bmjopen.bmj.com/content/suppl/2015/08/27/bmjopen-2015-008709supp-video1.mp4

Data supplement 3 - Online video 2: http://bmjopen.bmj.com/content/suppl/2015/08/27/bmjopen-2015-008709supp_video2.mp4

5. **PAT PLOT** http://www.cebm.net/pat-plot/

PaT plot is a graphical method of depicting the components of complex interventions. It is described in: Perera R, Heneghan C, Yudkin P. Graphical method for depicting randomised trials of complex interventions. BMJ 2007;334:127–9.

In randomised controlled trials, interventions may have several components, for example interviews, leaflets, group educational sessions, information packs, etc. This simple program any randomised trial to be depicted graphically no matter how many components are in the interventions. It will standardise the construction process and ensure every step is covered. Once created, a PaT Plot is easy to interpret and allows clear comparisons between different arms of a trial.

Examples of the display:

Timeline	Control	Meter: less intensive self- monitoring	Meter: more intensive self- monitoring
Pre-randomisation nurse training		a	
Pre-randomisation assessment visit		b	
Randomisation			(4)
Baseline, 2 weeks after assessment	Са	b d a	b e
2 weeks after baseline			f
2 weeks before 3,6,and 9 month consultation	g		
1,3,6 and 9 months from baseline	h	(i)	(j)
12 months	Measurement of outcomes		

a	Nurse training: 6 days of case based training over 5 weeks
b	Assessment visit, 45mins.
(c)	Nurse consultation, 45 mins. Setting of goals and review of diet, physical activity and medication. Patients asked not to use a meter.
а	Action planning diary to record self care goals
b	Blood glucose meter
d	Nurse consultation, 45 mins. Goal setting and review. Patients taught to use meter according to a specified protocol. Not told how to interpret blood glucose readings.
С	Blood glucose monitoring diary, to record blood glucose results.
e	Nurse consultation, 45 mins. Goal setting and review. Patients taught to use meter and to interpret results. Encouraged to explore effect of specific activities on blood glucose levels.
d	Diary combining action planning and blood glucose monitoring. Each page sets goals, achievements, barriers etc against concurrent blood glucose results.
f	Phone call from nurse to reinforce use of monitor and discuss any problems
g	Patient attends blood test at surgery to measure HbA1c.
h	Nurse consultation, 20 mins. Goal setting and review. HbA1c results reviewed as showing impact of self-care activities on glycaemic control.
i	Nurse consultation, 20 mins. Blood glucose values reviewed as showing impact of self-care activities on glycaemic control.
j	Nurse consultation, 20 mins. Blood glucose values reviewed and diary used to encourage recognition of relationship between behaviour and blood glucose results.

https://msdlt.physiol.ox.ac.uk/randomizedTrialsWeb/;jsessionid=8368664660A1492D64412C2BBC7 85349 direct access to the PatPlot tool/calculator

6. PHOTOGRAPHS (with decrptive text)

 Henriksen M, Klokker L, Graven-Nielsen T, Bartholdy C, Schjødt Jørgensen T, Bandak E, Danneskiold-Samsøe B, Christensen R, Bliddal H. Exercise therapy reduces pain sensitivity in participants with knee osteoarthritis: a randomized controlled trial The FITE-OA program. Arthritis Care Res (Hoboken). 2014; 66(12):1836-1843.





 da Luz MA Jr, Costa LO, Fuhro FF, Manzoni AC, Oliveira NT, Cabrai CM. Effectiveness of mat Pilates or equipment-based Pilates exercises in patients with chronic nonspecific low back pain: a randomized controlled trial. Phys Ther. 2014; 94(5):623-631.







7. PROTOCOL AS A PUBLISHED PAPER

 White PD, Goldsmith KA, Johnson AL, Potts L, Walwyn R, DeCesare JC, et al. Protocol for the PACE trial: a randomised controlled trial of adaptive pacing therapy, cognitive behaviour therapy, graded exercise as supplements to specialist medical care alone for patients with chronic fatigue syndrome/myalgic encephalomyelitis or encephalopathy. BMC Neurol. 2007; 6: doi: 10.1186/1471-2377-7-6.

On-line trial protocol published on BioMed Central: http://bmcneurol.biomedcentral.com/articles/10.1186/1471-2377-7-6

Hurley DA, Hall AM, Currie-Murphy, Pincus T, Kamper S, Maher C, McDonough SM, Walsh NRE, Guerin S, Segurado R, Matthews. Theory-driven group-based complex intervention to support self-management of osteoarthritis and low back pain in primary care physiotherapy: protocol for a cluster randomised controlled feasibility trial (SOLAS). BMJ Open. 2016;
 6:e010728 doi:10.1136/bmjopen-2015-010728

On-line trial protocol and supplementary data files published on BMJ Open:

http://bmjopen.bmj.com/content/6/1/e010728.full#T2

http://bmjopen.bmj.com/content/suppl/2016/01/21/bmjopen-2015-010728.DC1/bmjopen-2015-010728supp1.pdf

http://bmjopen.bmj.com/content/suppl/2016/01/21/bmjopen-2015-010728.DC1/bmjopen-2015-010728supp2.pdf

 Bennell KL, Hunt MA, Wrigley TV, Hunter DJ, Hinman RS. The effects of hip muscle strengthening on knee load, pain, and function in people with knee osteoarthritis: a protocol for a randomised, single-blind controlled trial. BMC Musc Dosord. 2007; 8:121 doi:10.1186/1471-2474-8-121 FOR Bennell KL et al. Hip strengthening reduces symptoms but not knee load in people with medial knee osteoarthritis and varus malalignment: a randomised controlled trial.

Osteoarthritis Cartilage. 2010; 18(5): 621-628

8. SMARTPHONE APP

Example paper:

 Hupperets MDW, Verhagen EALM, van Mechelen W. Effect of unsupervised home based proprioceptive training on recurrences of ankle sprain: randomised controlled trial. BMJ. 2009; 339:b2684.

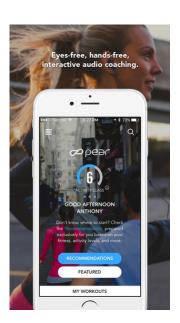
This app (OEFENINGEN), which is available through Apple App Store and iTunes, demonstrates the exercises involved in the intervention, including their schedule.

http://www.schemaatje.nl/fitness-oefeningen website with embedded videos for correct exercise performance (Netherlands)

• Kennelly MA, Ainscough K, Lindsay K, Gibney E, McCarthy M, McAuliffe FM. Pregnancy, exercise and nutrition research study with smart phone app support (Pears): study protocol of a randomized controlled trial. Contemporary Clinical Trials. 2016; 46: 92-99.

The trial used the PEARS PERSONAL COACH SMARTPHONE APP (from Apple App Store and iTunes) https://itunes.apple.com/us/app/pear-personal-coach-interactive/id563723189?mt=8





9. TABLES OR APPENDICES (within the manuscript)

• Cleland JA, Mintken P, McDEVITT a, Bieniex M, Carpenter K, Kulp K, Whitman JM. Manual Physical Therapy and Exercise Versus Supervised Home Exercise in the Management of

Patients With Inversion Ankle Sprain: A Multicenter Randomized Clinical Trial. JOSPT. 2013; 43(7): 443-455

Appendix A describes guidelines for exercise progression and Appendix B provides photographs and descriptions on manual techniques.

10. TRAINING/INTERVENTION MATERIALS/MANUALS - AS A SEPARATE PUBLISHED PAPER

 Hallgren HCB, Holmgren T, Oberg B, Johansson K, Adolfsson LE. A specific exercise strategy reduced the need for surgery in subacromial pain patients. BJSM. 2014; 48(19): 1431-1436

Exercise program published in: Holmgren T et al. Effect of specific exercise strategy on need for surgery in patients with subacromial impingement syndrome: randomised controlled study. BMJ. 2012;344:e787 doi: 10.1136/bmj.e787

11. TRAINING MATERIALS/MANUALS -ON A WEBSITE

 White PD, Goldsmith KA, Johnson AL, Potts L, Walwyn R, DeCesare JC, et al. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): a randomised trial. Lancet 2011; 377: 823-36.

http://www.wolfson.qmul.ac.uk/current-projects/pace-trial/#trial-information – all treatment and participant manuals are available at this web-link, as well as participant newsletters