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Psychological therapies (remotely delivered) for the management of chronic and recurrent pain in children and adolescents

Emma Fisher[1], **Emily Law**[2], **Tonya M Palermo**[2], and **Christopher Eccleston**[1]

[1]Centre for Pain Research, University of Bath, Bath, UK

[2]Anesthesiology and Pain Medicine, University of Washington, Seattle, Washington, USA

Abstract

This is the protocol for a review and there is no abstract. The objectives are as follows:

To determine the effectiveness of psychological therapies delivered remotely compared to waiting-list, treatment-as-usual, or active control for the management of chronic pain in children and adolescents.

BACKGROUND

Description of the condition

Chronic pain is prevalent during childhood and adolescence (Perquin 2000). Epidemiological studies report that girls experience more pain in comparison to boys, and that pain increases during early adolescence (King 2011). Further, risk of developing a pain condition is higher for children of a lower socioeconomic status (King 2011). The most commonly reported pain problems are headache, recurrent abdominal pain, musculoskeletal pain, and back pain (King 2011). Some children with chronic pain report high levels of pain as well as depression and anxiety (Gauntlett-Gilbert 2007; Kaczynski 2011). Children can also suffer impairments in their physical and social functioning, such as attending school (Cohen 2011). The detrimental effects of chronic pain can also impact their parents who report significant distress and anxiety (Jordan 2007; Maciver 2010).

Contact address: Emma Fisher, Centre for Pain Research, University of Bath, Claverton Down, Bath, BA2 7AY, UK. e.a.fisher@bath.ac.uk.

CONTRIBUTIONS OF AUTHORS

Emma Fisher (EF) will oversee authoring of this manuscript, search, obtain, and select relevant studies, enter data into RevMan, carry out and interpret analysis, and be responsible for updating the review.
Emily Law (EL) will search, obtain and select relevant studies, carry out and interpret analysis, and draft the final manuscript.
Tonya Palermo (TP) will carry out and interpret the analysis and draft the final manuscript.
Christopher Eccleston (CE) will carry out and interpret the analysis, arbitrate selection of studies, and draft the final manuscript.

DECLARATIONS OF INTEREST

None known.

Description of the intervention

Psychological therapies, delivered individually or in groups to children and families, significantly reduce pain and disability in youths with chronic pain (Eccleston 2014). However, many young people do not receive psychological treatments for chronic pain due to barriers such as a shortage of providers, expense, and geographic distance from treatment centres (Palermo 2013; Peng 2007). This has led to consideration of innovative methods of delivery and calls to assess whether psychological interventions can be effectively delivered remotely using technology such as the Internet (Palermo 2009). The Internet is widely available to a large number of children and adolescents. For example in the UK 83% of households had Internet access in 2013 (ONS 2013), in the US 72% (USDC 2013) and in Australia 79 % (ABS 2012) meaning that access to health information or treatments is potentially more easily available.

Different terms are used within this growing field, broadly described as e-health, telemedicine, telecare, minimal therapist contact, and distance treatment. Here, we adopt "remotely delivered therapies" to define psychological therapies delivered without, or with limited face-to-face contact with the therapist. Therapies will typically be delivered via technology, principally the Internet, but could also be delivered via telephone, written materials, or standalone computer programmes. Therapies may also be combined or blended by including both face-to-face and remote components. These interventions can be delivered in the home or community (outside the clinic or hospital setting) without the physical presence of a therapist.

How the intervention might work

Psychological therapies (as discussed in Eccleston 2014) are used in paediatric pain practice to reduce pain symptoms, disability, and negative mood associated with pain conditions, and to modify social-environmental factors to enhance the child's adaptive functioning. This field is currently dominated by cognitive and behavioural therapies that incorporate components such as relaxation, biofeedback, imagery, parent operant strategies, and coping skills training.

Recognising the advantages of reaching more children in their homes with remotely delivered interventions, earlier studies relied on low levels of technology, including written self-help manuals, portable biofeedback monitors, and relaxation audiotapes (e.g. Burke 1989; McGrath 1992). As technological advances became available to the masses, intervention delivery options expanded to personal computers via CD-ROM applications and then via Internet interventions. The delivery of psychological therapies over the Internet is becoming more common (March 2008; Richardson 2010; Tait 2010). The potential benefits to a successful programme include improved access, improved scale of coverage, and lower cost (Marks 2009; Palermo 2009). However, the change of a delivery mechanism from face-to face delivery to remote delivery solely by, or augmented with technology, arguably changes the content, intensity, and force of a treatment. The move away from delivery is not simply to change the route of intervention delivery to a remote method. Instead, the transformation of a treatment to a reliance on communication technology (instead of face-to-face interaction with a therapist) may involve critical changes in aspects

of the treatment thought crucial to its success. For example, treatment where a therapist is not present may influence treatment participation and impact treatment outcomes (Fry 2009).

There may also be different therapeutic opportunities available using interactive and communication technologies. As described in the behavioural change model for Internet interventions (Ritterband 2009), user characteristics interact with website characteristics to produce behaviour change. For example, internet-delivered therapies may work by better matching and designing technology to maximise the therapeutic benefits (e.g. 24 hour access to skills training), or there may be a blend to these solutions that function differently dependent upon user characteristics. Typically, authors are not explicit about how the technology may have changed the intervention itself, but earlier remotely delivered therapies were informed by the question of equivalence: can an remotely delivered therapy perform as well as a face-to-face therapy? More recent trials treat the remotely delivered therapy as a package and ask: can a remotely delivered therapy achieve better outcomes than a comparison group or can remotely delivered therapy be efficacious in achieving positive change in meaningful treatment outcomes?

Why it is important to do this review

Psychological therapies delivered remotely (principally but not exclusively via the Internet) have now developed into stand alone treatments, and are investigated as stand alone treatments. A Cochrane review has previously summarised evidence of psychological therapies for the management of chronic pain in children and adolescents (Eccleston 2014). This was first authored in 2003, and updated in 2009, 2012, and most recently in 2014. Earlier updates combined remote and face-to-face office-based treatment delivery. However, we believe it is important to separate them so that evidence can be separately evaluated. This review should be considered a sister review to the Eccleston 2014 update which excludes treatments delivered remotely. A similar distinction has also been made in the Cochrane reviews on psychological therapies for the management of chronic pain in adults: face-to-face (Williams 2012) and Internet delivered (Eccleston 2012).

OBJECTIVES

To determine the effectiveness of psychological therapies delivered remotely compared to waiting-list, treatment-as-usual, or active control for the management of chronic pain in children and adolescents.

METHODS

Criteria for considering studies for this review

Types of studies—We will search for randomised controlled trials (RCTs) that investigate psychological therapies, delivered remotely.

Types of participants—We will include children and adolescents under the age of 18 years in this review. The intervention must primarily target the child or adolescent with chronic or recurrent pain, defined as pain lasting for three months or longer. Pain conditions

will typically (but not exclusively) fall into the categories of headache, musculoskeletal pain, neuropathic pain, and recurrent abdominal pain. We will exclude pain associated with life-limiting (e.g. cancer) or other (e.g. diabetes) conditions. There must be 10 or more participants in each arm of the trial at the extracted time-point of post-treatment or follow-up.

Types of interventions—Interventions must be primarily psychological, include recognisable psychotherapeutic content, or be based on an existing psychological framework. Interventions must aim to change cognition or behaviour, and must include at least one comparator arm. Therapies must aim to improve pain outcomes and function, therapies that solely aim to manage the child or adolescent's mood will be excluded. The psychological therapy must be delivered remotely, using technology such as the Internet, computer programme, smartphone application, or telephone. Therapies using technology such as audiotapes or written manuals at home are included in Eccleston 2014, and will not be included in this review. Therapies that use blended treatments, combining both face-to-face contact and a remote component will also be considered for inclusion in this review. However, the intention (stated or inferred) should be to deliver the majority of the treatment remotely from the therapist. As a guide, we will exclude studies that conduct over 30% of contact time (assessment or therapy) face-to-face. We will exclude interventions that have the primary aim to monitor symptoms or aid communication (such as with a treatment team).

Types of outcome measures

Primary outcomes: Four primary outcomes will be extracted from each study: pain symptoms, disability, depression, and anxiety. Adverse events will also be reported.

Secondary outcomes: Satisfaction with treatment will be extracted as a secondary outcome.

Search methods for identification of studies

Electronic searches—We will search the following databases for studies from inception to the present day,

- CENTRAL
- MEDLINE (OVID)
- EMBASE (OVID)
- PsycINFO (OVID

A search strategy for MEDLINE has been devised and this will be adapted for the other databases listed (see Appendix 1).

Searching other resources—We will carry out a reference search and citation search of all included studies in order to identify additional studies not identified in our electronic search. We will contact authors for any further studies. Relevant reviews retrieved by the database searches will be examined to identify any further trials. In addition, we will search trial registries, including the metaRegister of controlled trials (mRCT) (www.controlled-

trials.com/mrct/), ClinicalTrials.gov (clinicaltrials.gov), and the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/en/) for trials. There will be no limitation on publication date or on language and we will assess non-English papers and translate as necessary.

Data collection and analysis

Selection of studies—Two authors will independently select and read potential studies for inclusion. A third author will arbitrate any disagreements. We will select studies according to the following criteria,

1. Children under the age of 18 years with a chronic pain condition.
2. N >10 in each arm of the trial at each extracted time-point.
3. A primarily psychological therapy must be used in at least one arm of each included trial.
4. Therapies must have a primary aim to change thoughts or behaviours of the child to assist with the management of, or coping with chronic pain.
5. The therapy must be principally delivered remotely however, we will also consider trials that include a remotely delivered component that is combined with face-to-face contact. To promote transparency of the search and systematic review process, we will produce a PRISMA flow diagram, as recommended in Chapter 6 of the Cochrane Handbook (Higgins 2011).

Data extraction and management—Two authors will independently extract data from the studies. Disagreements will be first be discussed by the two authors, if no agreement can be found then a third author will arbitrate. First, study characteristics will be extracted from each of the studies. These will include patient demographics, characteristics of the psychological therapies including delivery type, duration of treatment, when and where treatment is accessed, engagement in treatment, type of control condition, and follow-up periods. Second, data for each of the four primary outcomes and secondary outcome will be extracted and entered into a meta-analysis. Outcome data will be extracted at post-treatment and follow-up. If studies report incomplete data, we will contact the authors. We will collect characteristics of the included studies in sufficient detail to populate a table of 'Characteristics of included studies'.

Assessment of risk of bias in included studies—We will assess risk of bias using the Cochrane Collaboration's 'Risk of bias' tool (Higgins 2011). This outlines four biases: selection bias, detection bias, attrition bias, and reporting bias. Selection bias will be judged by random sequence generation and allocation bias. Detection bias will be judged by blinding of personnel and participants, and blinding of outcome assessors. Attrition bias will be judged by incomplete outcome reporting. Finally, reporting bias is used to judge selective reporting.

If possible, we will use GRADE to summarise the quality of evidence for each outcome post-treatment and at follow-up. Two summary of findings tables will be produced; one for

headache outcomes and one for mixed conditions. Only the seven most important outcomes can be included in each 'Summary of findings' table, therefore, we will select the seven outcomes that include the highest number of participants. This uses a four-tiered rating system to rate outcomes as 'high', 'moderate', 'low', or 'very low'. Outcomes are assessed on risk of bias, inconsistency, indirectness, imprecision, and publication bias (Balshem 2011; Higgins 2011). High quality is given when "we are very confident that the true effect lies close to that of the estimate of the effect", moderate quality is judged when "we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different", low quality is given when "our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect", and very low quality is judged when "we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect" (p. 404, Balshem 2011).

Measures of treatment effect—We will categorise chronic pain conditions into headache and mixed conditions. Mixed conditions refer to painful conditions such as musculoskeletal pain, neuropathic pain, and recurrent abdominal pain. Due to the small number of studies in this area, we will combine these conditions in analyses to provide the overall effectiveness of psychological therapies delivered remotely. If a study reports both headache and mixed conditions, we will enter data into both analyses where appropriate. Pain symptoms, disability, depression, anxiety, and satisfaction with treatment will be analysed at two time-points (post-treatment and follow-up). Satisfaction with treatment will be defined as any measure, based on self-report (child or parent), that aims to assess how useful the treatment was, satisfaction with outcome of therapy, and likability and preference for the treatment. If both child and parent report satisfaction with treatment, the child report will be preferentially extracted. When studies use more than one measure for a given outcome, we will extract the most reliable or commonly used. Post-treatment is defined as the time-point immediately following treatment. Follow-up is defined as the time-point between 3–12 months following post-treatment. If more than one time-point is available, the later of the two will be extracted. Due to this novel method of delivery of psychological interventions, we predict that there will be a small number of studies to include in analyses. Therefore, studies will not be categorised by therapy type or control type (i.e. active vs. wait-list) and results will be directly comparable to Eccleston 2014. In total, there will be 20 possible analyses, categorised by four headings:

1. Treatment vs. control, post-treatment, headache conditions.
2. Treatment vs. control, follow-up, headache conditions.
3. Treatment vs. control, post-treatment, mixed conditions.
4. Treatment vs. control, follow-up, mixed conditions.

Data synthesis—We will pool data using Review Manager 5.2 (RevMan 2012). Headache conditions typically report dichotomous data for pain symptoms. This is defined by a 50% reduction of pain symptoms. Mixed conditions (e.g. musculoskeletal pain, neuropathic pain, and recurrent abdominal pain) typically report continuous data for pain

symptoms. For dichotomous data, we will calculate risk ratios (RRs), 95% confidence intervals (CIs) and number needed to treat to benefit (NNTB). For continuous data, we will report standardised mean differences (SMDs) and 95% CIs. Mantel-Haenszel methods will be used to analyse dichotomous data and random-effects models will be used to analyse continuous data.

Subgroup analysis and investigation of heterogeneity—If possible, we will carry out a subgroup analysis of the technology type and intensity used in the trials (e.g. Internet versus telephone; low intensity technology versus high intensity technology). Further, we will attempt to determine the difference in effect between trials that include a human support component (blended therapy) versus those without human support that are exclusively delivered remotely. Additional support during trials delivered via the Internet has been found to influence outcomes of participants (Law 2012). This will allow us to make informed recommendations for future research and practice.

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REFERENCES

Australian Bureau of Statistics. [accessed October 2013] Use of Information Technology. www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/1301.0~2012~Main%20Features~Use%20of%20information%20technology~174

Balshem H, Helfand M, Schunemann HJ, Oxman AD, Kunz R, Brozek J, et al. GRADE guidelines 3. Rating the quality of evidence. Journal of Clinical Epidemiology. 2011; 64(4):401–406. [PubMed: 21208779]

Burke EJ, Andrasik F. Home- vs. clinic-based biofeedback treatment for pediatric migraine: results of treatment through one-year follow-up. Headache: The Journal of Head and Face Pain. 1989; 29(7): 434–440.

Cohen LL, Vowles KE, Eccleston C. The impact of adolescent chronic pain on functioning: disentangling the complex role of anxiety. Journal of Pain. 2010; 11(11):1039–1046. [PubMed: 20015706]

Eccleston C, Fisher E, Craig L, Duggan GB, Rosser BA, Keogh E. Psychological therapies (internet delivered) for the management of chronic pain in adults. Cochrane Database of Systematic Reviews. 2012; (Issue 10)

Eccleston C, Palermo TM, Williams ACDC, Lewandowski Holley A, Morley S, Fisher E, et al. Psychological therapies for the management of chronic and recurrent pain in children and adolescents. Cochrane Database of Systematic Reviews. 2014; (Issue 5)

Fry JP, Neff RA. Periodic prompts and reminders in health promotion and health behavior interventions: systematic review. Journal of Medical Internet Research. 2009; 11(2):e16. [PubMed: 19632970]

Gauntlett-Gilbert J, Eccleston C. Disability in adolescents with chronic pain: Patterns and predictors across different domains of functioning. Pain. 2007; 131(1–2):132–141. [PubMed: 17267129]

Higgins, JPT.; Green, S., editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration. 2011. Available from www.cochrane-handbook.org.

Jordan AL, Eccleston C, Osborn M. Being a parent of the adolescent with complex chronic pain: an interpretative phenomenological analysis. European Journal of Pain. 2007; 11(1):49–56. [PubMed: 16458550]

Kaczynski KJ, Simons LE, Lewis Claar R. Anxiety, coping, and disability: a test of mediation in a pediatric chronic pain sample. Journal of Pediatric Psychology. 2011; 36(8):932–941. [PubMed: 21551124]

King S, Chambers CT, Huguet A, MacNevin RC, McGrath PJ, Parker L, et al. The epidemiology of chronic pain in children and adolescents revisited: a systematic review. Pain. 2011; 152(12):2729–2738. [PubMed: 22078064]

Law EF, Murphy LK, Palermo TM. Evaluating treatment participation in an internet-based behavioral intervention for pediatric chronic pain. Journal of Pediatric Psychology. 2012; 37(8):893–903. [PubMed: 22511033]

Maciver D, Jones D, Nicol M. Parents' experiences of caring for a child with chronic pain. Qualitative Health Research. 2010; 20(9):1272–1282. [PubMed: 20406993]

March S, Spence SH, Donovan CL. The efficacy of an internet-based cognitive-behavioral therapy intervention for child anxiety disorders. Journal of Pediatric Psychology. 2008; 34(5):474–487. [PubMed: 18794187]

Marks I, Cavanagh K. Computer-aided psychological treatments: evolving issues. Annual Review of Clinical Psychology. 2009; 5:121–141.

McGrath PJ, Humphreys P, Keene D, Goodman JP, Lascelles MA, Cunningham SJ, et al. The efficacy and efficiency of a self-administered treatment for adolescent migraine. Pain. 1992; 49:321–324. [PubMed: 1408297]

Office for National Statistics. [accessed October 2013] Internet access - households and individuals. 2013. www.ons.gov.uk/ons/dcp171778_322713.pdf

Palermo TM, Wilson AC, Peters M, Lawandowski A, Somhegyi H. Randomized controlled trial of an internet delivered family cognitive-behavioral therapy intervention for children and adolescents with chronic pain. Pain. 2009; 146(1–2):205–213. [PubMed: 19695776]

Palermo, TM. Remote management of pediatric pain. In: Schmidt, RF.; Gebhart, GF., editors. Encyclopedia of Pain. 2nd Edition. New York: Springer; 2013. p. 3389-3393.

Peng P, Stinson JN, Chiniere M, Dion D, Intrater H, Lefort S, et al. STOPPAIN Investigators Group. Dedicated multidisciplinary pain management centres for children in Canada: the current status. Canadian Journal of Anesthesia. 2007; 54(12):985–991. [PubMed: 18056207]

Perquin CW, Hazebroek-Kampscheur AAJM, Hunfeld JAM, Bohnene AM, van Suijlekom-Smit LWA, Passchier J, et al. Pain in children and adolescents: a common experience. Pain. 2000; 87(1):51–58. [PubMed: 10863045]

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). 5.2. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration; 2012.

Richardson T, Stallard P, Velleman S. Computerised cognitive behavioural therapy for the prevention and treatment of depression and anxiety in children and adolescents: a systematic review. Clinical Child and Family Psychological Review. 2010; 13(3):275–290.

Ritterband LM, Thorndike FP, Cox DJ, Kovatchev BP, Gonder-Frederick LA. A behavior change model for internet interventions. Annals of Behavioral Medicine. 2009; 38(1):18–27. [PubMed: 19802647]

Tait RJ, Christensen H. Internet-based interventions for young people with problematic substance use: a systematic review. Medical Journal of Australia. 2010; 192(11 Suppl):S15–S21. [PubMed: 20528701]

US Department of Commerce. [accessed October 2013] Computer and Internet Use in the United States; population characteristics. www.census.gov/prod/2013pubs/p20-569.pdf

Williams ACDC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database of Systematic Reviews. 2012; (Issue 11)

APPENDICES

Appendix 1. MEDLINE search strategy

1. exp Pain/

2. exp Headache Disorders/
3. Fibromyalgia/
4. (pain* or headache* or migraine* or fibromyalgia* or neuralgia*).tw.
5. or/1–4
6. exp Child/
7. Adolescent/
8. Infant/
9. (child* or infant* or baby or babies or preschooler* or pre-schooler* or toddler* or schoolchild* or girl* or boy* or adolescen* or teen*).tw.
10. or/6–9
11. exp Internet/
12. (Internet or web or blog* or “social media” or online or www or email* or e-mail*).tw.
13. exp Telecommunications/
14. (telemedicine or tele-medicine).tw.
15. (telehealth or tele-health).tw.
16. (ehealth or e-health).tw.
17. (mobile health or mhealth or m-health).tw.
18. ICT.tw.
19. ((inform* or communicat* or interact*) adj6 (computer* or technolog* or software)).tw.
20. ((health* or treat* or therap* or intervention* or assist* or selfmanag* or self-manag*) adj6 (computer* or technolog* or software)).tw.
21. “world wide web”.tw.
22. (telephone* or phone* or mobile* or cellphone* or apps or text* or SMS or smartphone*).tw.
23. (virtual reality or augmented reality or VR or AR).tw.
24. or/11–23
25. 5 and 10 and 24
26. randomized controlled trial.pt.
27. controlled clinical trial.pt.
28. randomized.ab.
29. placebo.ab.

30. drug therapy.fs.
31. randomly.ab.
32. trial.ab.
33. or/26–32
34. exp animals/ not humans.sh.
35. 33 not 34
36. 25 and 35