	psychosocial function of a new personal FM system, the Phonak EduLink, when used in mainstream classroom environments by children with **APD.**	Intervention group: Ten children (eight male, two female) with a positive diagnosis of APD. Mean age of 11 years, 8 months. Control group: Thirteen children (nine male and four female) with normal hearing & no APD. Mean age of 10 years, 6 months. Intervention group fitted binaurally with Phonak EduLink FM systems. Used for approx. 5 months Use time In school for all lecture based classroom situations Home use was not required but encouraged Fitting Fitted by researchers and instructed on how to use the system Outcome measures • Speech-perception: Hearing in Noise Test (HINT) • Academic performance: listening inventory for education (LIFE) and screening instrument for targeting educational risk (SIFTER)	at the post-fit evaluation for the APD group in the academic domain.(subjectively graded by parents and not teachers) Results of the LIFE self-report evaluation revealed that students in the APD group significantly improved for questions 1, 3, and 5, which relate to the following classroom situations: teacher talking in front of room, teacher talking with back turned, and other students making noise Speech perception: benefit of 3.62 dB (SD_4.63) from use of the FM system Psychosocial: student reported comparisons reflect improvements in psychosocial function for the APD group, specifically in areas related to locus of control, anxiety, depression, and interpersonal relationships.	markedly different from the estimated effect) Small sample of convenience, no blinding, subjective measures used, lack of precision due to no confidence intervals, The present study does not provide data for establishing the duration of time necessary for an adequate trial period of FM use.

		• Psychosocial: behaviour assessment system for children: second edition (BASC-2)		
Keith and Purdy [7]	No aim or objective, however, a "learning outcome" is provided. The participant will be able to (1) list the assistive and therapeutic benefits of remote microphone hearing aids for children with auditory processing disorder, and (2) Explain the importance of expert intervention to support teachers to achieve successful outcomes with amplification for children with APD.	**Editorial** Opinion based, no aims or methods as to how literature was chosen. Predominantly gives an overview of some study findings and what FM systems are.	*"Personal remote microphone hearing aids are currently the only evidence-based amplification treatment shown to improve hearing in classrooms for children with APD."* The literature cited to back this up includes a study published on an FM manufacturer's website, 2 case-control studies, a conference presentation and a quasi-randomised trial (level III evidence). This is not enough to make claims of it being an evidence based practice. There are major biases in these study designs, and further large scale RCTs are needed.	Level: N/A **Quality = Very Low** (The true effect is probably markedly different from the estimated effect Editorial – authors opinion, not based on stats. Can't verify methods.
Rosenberg [8]	N/A	Abstract only - Unable to obtain full text article	Can't comment. Abstract doesn't provide any results.	N/A

Schafer, Mathews [9]	To examine the potential benefit of a frequency modulation (FM) system for 11 children diagnosed with autism spectrum disorders (ASD), attention-deficit hyperactivity disorder (ADHD), or both disorders	**Case-Control study – repeated measures design** <u>Intervention group:</u> 11 children (7 ASD and 4 ADHD) (9-12 years) were included in five separate investigative measures: • Speech recognition in noise • classroom observations of behaviour • teacher questionnaire to assess educational need • teacher questionnaire to assess listening behaviours • Social validation measures (i.e., informal questionnaires) with the teacher and each participant <u>Control group:</u> 11 gender- and age-matched (9-12 years), typically functioning peers participated in the speech recognition in noise measure in a no-FM system condition. All recruited from a single private school classroom (lack of generalisability and causes sampling bias)	Not all participants completed all trials (x2) so their data was removed. 20% removed the FM receiver for some period of time because • the receiver was ‘‘bothering his or her ear(s)” • the receiver was ‘‘uncomfortable’’ • the child was asked by the teacher to remove the receiver and leave the room for behaviour issues Speech recognition in noise varied across participants. Improvement of at least 3dB was seen in one of the 2 trial sessions. <u>On-task behaviours</u> were significantly higher in both FM trial periods as compared to both no-FM trial periods ($p < .05$). <u>Off-task behaviour:</u> only 2/8 codes were significant (Does not follow teacher direction, but engages in distractible behaviours and Does not sit quietly when expected or asked, but instead,	**Level: III-2** **Quality: Low** (The true effect might be markedly different from the estimated effect) Small sample of convenience (2 drop outs), no blinding, and subjective measures used, lack of precision due to no confidence intervals and descriptive statistics used in some instances. Limitations provided by author 1) unable to generalise to public school students 2) Participants in this study were all high-functioning children with relatively few behavioural issues 3) Social consequences of

		Ear-level FM receivers worn on both ears (i.e., Phonak iSense Micro FM receivers), <u>Multiple trial periods</u> Trial 1 = 2 weeks Trial 2 = 3 weeks Only 45 minutes per day	engages in other distractible behaviours) <u>Formal questionnaire results</u> SIFTER questionnaire: no significant differences in the teacher ratings from the no-FM to the FM system conditions (i.e., $p > .05$) for all comparisons. Children's Auditory Performance Scale: small to medium effect sizes. Not all significant.	wearing an FM system 4) Control group only used for speech recognition measures 5) Trial periods were short – hard to determine what effect that might have 6) Participants did not receive full audiological evaluations just prior to the study Future research is warranted to examine potential benefits of FM system use for children with ASD and ADHD in other school environments.
Schafer, Florence [10]	To provide research evidence to support the educational hearing needs of APD, ASD, ADHD and dyslexia populations.	**Combined Editorial/Narrative Review** No methods – only includes evidence in support of FM systems (this is inherently flawed)	Descriptive results of reviewed studies include: *"Across most of the studies, there is a clear improvement in speech recognition performance in background noise in conditions with versus without the FM*	Level: N/A **Quality = Very Low** (The true effect is probably markedly different from the estimated effect

		• Provide an overview of the auditory deficits reported for these populations • Review published studies that support remote-microphone, hearing-assistance technology • Recommend an evidence-based assessment and fitting protocol • Present a case study to demonstrate how the recommended protocols may be used to assess and fit remote microphone HAT on children with normal hearing and disabilities.	*system, with FM gains ranging from 17% to 86% (pretty significant variation – shows uncertainty in results) for fixed-intensity stimuli and 6 to 10 dB for adaptive test stimuli."* *"Results of these questionnaires lend strong (subjective questionnaires are never considered strong evidence) support for the use of FM systems in order to improve communication, comprehension, attention, and listening abilities, particularly in noisy or reverberant environments."* Have copied table with evidence in this paper and pasted below. In total, only 29 participants with ASD have been investigated. This is not a significant number to base practice off.	Editorial – authors opinion, not based on stats. Can't verify methods. Author is the editor of the journal that published the paper. Cannot tell whether peer reviewed. High level of bias
Schafer, Traber [11]	A series of case studies on children diagnosed with APDs, ADHD, ASDs, and/or language disorders will be presented to (1) support specific remote microphone-	**Case study -** Unable to obtain full text article Can't comment on methods 12 participants included	Results taken from the Table provided in Schafer, Florence [10] 1. Sentence recognition in babble at -5 dB SNR: Right ear FM, left ear FM and bilateral FM significantly better than no-FM condition by an average of 65	**Level: IV** Quality: Difficult comment with only abstract details. Likely low to very low due to sample size, lack of generalisability and

	fitting procedures and (2) to report speech-recognition performance in noise; listening comprehension; and participant-, parent-, and teacher-rated listening behaviors following a trial period with the technology.		to 86% 2. Listening comprehension in classroom noise at -5 dB SNR: Significant improvement with FM vs. no FM on main idea, details, reasoning, vocabulary, and understanding messages subtests 3. Student LIFE-R (n=8) and CHILD (n=7): Significant benefit of FM at school in classroom situations on LIFE; significant benefit of FM at home when in noise and in social situations on the CHILD 4. Parent CHILD: Significant benefit of FM in quiet, in noise, at a distance, in social situations, and for media	high possibility of bias due to study design
Rance [12]	No aim/objective	**Opinion piece/Journal club**	Discusses a couple of papers relevant to the area. States that Schafer paper should be interpreted with caution due to the study limitations (which are listed above in the Schafer study). Makes a good point about the Schafer study: *"Participants in this study were all high-functioning children with*	Level: N/A Quality: N/A

			relatively few behavioural issues. It could be argued that youngsters at the other end of the disability spectrum would have an even greater need for better hearing, but expecting these kids to tolerate any device, even for a short period of time, may be unrealistic."	
Rance, Chisari [13] Dr Rance is associate professor at the University of Melbourne, where he coordinates the Master of Clinical Audiology Program.	to objectively evaluate the effect of auditory intervention on the stress response in children	**Case study – pre-test/post-test outcomes** Twenty-six children (6 girls) with ASD participated 16 children (ASD1-16) participated in Study A (mean age 9.5 years) 10 children (ASD17-26) took part in Study B (mean age 14.9 years) Children were assigned to each Study based on their age and educational setting. Convenience sample, non-randomised Participant anxiety levels were evaluated using the Achenbach System of Empirically Based Assessment. For children in Study A, the parents completed the Child Behaviour	Study A *Speech Perception* Mean score for the aided listening condition (M = 76.5, SD = 8.2%) was significantly higher than for the unaided (M = 55.5%, SD = 13.8% (P < 0.001). *Hearing Disability* Hearing disability ratings for the Background Noise subscale were significantly lower for the device-aided listening condition (M = 28.7%, SD = 11.3%) than for the unaided (M = 51.6%, SD = 20.0% (P < 0.001). Ease of Communication subscale were lower for the aided listening condition (M = 15.0%, SD = 15.7%) than for the unaided (M = 26.5%, SD = 21.3% (P = 0.025).	**Level: IV** **Quality: Low** (The true effect might be markedly different from the estimated effect) Small participant numbers, missing parent data, only high functioning children involved, non-randomised, no control group – all these factors lead to uncertainty around results

		Checklist (CBCL) and for Study B, the Teacher Report Form (TRF) was used. Hearing disability survey (Abbreviated Profile of Hearing Aid Benefit) and an audiometric assessment Study A: Each participant was then afforded 1–2 weeks of device experience (M = 8.8 days, SD = 2.1 days) in which the listening system was worn at school and home for 4–6 h per day. Salivary Cortisol concentrations were obtained from saliva samples collected before and after each structured listening session. Study B: Each child participated in three test sessions carried out in a standard classroom. The first involved audiometric assessment carried out one-on-one in a quiet (empty) classroom and expectoration training as per Study A. Subjects then underwent two, 20 min listening sessions in a standard (otherwise unoccupied) classroom	*Parent-Reported Anxiety* Only 6 parents completed the questionnaire. Only 25% reported changes in anxiety level. *Cortisol Concentration* comparison of within-session cortisol change for each individual revealed a significant difference between unaided and aided listening conditions (P = 0.003). Study B *Cortisol Concentration* Comparison of within-session cortisol change for each individual revealed a significant difference between unamplified change and amplified change (P = 0.005) Participants with the poorest functional hearing ability showed the highest physiological stress levels in structured listening/comprehension sessions and also demonstrated the greatest stress reduction with the provision of auditory intervention.	

Rance, Saunders [4]	To evaluate both monaural and binaural processing skills in a group of children with ASD and to determine the degree to which personal FM listening systems could ameliorate their listening difficulties.	**Case study - pre-test/post-test outcomes (control group only used to determine differences of baseline measures)** Intervention group: Twenty children with ASD participated (mean age 12 years, range 8 to 15.4 years). Only children with no known coexisting disabilities and Full-Scale IQ, Wechsler Intelligence Scale for Children values >70 were referred for the study. Control group: age- and sex-matched control participants was also evaluated. Age at data collection was within 12 months of the ASD partner. Outcome measures - Hearing disability questionnaire—the Abbreviated Profile of Hearing Aid Benefit (APHAB). - Basic auditory processing and functional hearing - Listening in Spatialized Noise test - Consonant-Nucleus-Consonant-Word test. Following this "unaided" assessment, the child was fitted with a Phonak Inspiro FM transmitter paired with iSense receivers (Phonak Org,	20 ASD and 20 normal controls <u>Hearing Disability Survey</u> Mean APHAB scores were significantly higher in this group than in controls across a range of perceptual and communication subscales (P < .001). <u>Auditory Temporal Processing</u> Detection of amplitude modulation in ASD subjects was significantly impaired relative to matched controls. <u>Spatial Processing</u> Mean spatial advantage for the ASD group was 9.2 ± 3.2 dB and that for the control group was 11.9 ± 1.4 dB (95% CI 1.0-4.4 dB; P = .003). <u>Open-Set Speech Discrimination</u> Speech perception in noise was poorer in participants with ASD than in matched controls (P = .009). **<u>FM Device Trial</u>** Only primary school group completed the device trial (other group used for baseline	**Level: IV** **Quality: Low** (The true effect might be markedly different from the estimated effect) Small participant numbers, only high functioning children involved, non-randomised, no comparison group – all these factors lead to uncertainty around results.

		Murten, Switzerland). Speech testing repeated after fitting of FM system. Day-to-day listening ability was investigated in the primary-school ASD group (n = 10) across a **6-week**, take home device trial. A balanced design (ABBA) was used, involving 2-week periods of device use (B) and 2-week periods of non-use (A) to allow for learning/experience effects. During "device-on" phases, the children (and teachers/parents) were encouraged to wear the system throughout the day. **Four to 6 hours of sustained use per day was typical.**	comparisons). 8/10 completed the study. FM device use afforded significant listening and communication benefits (P = .001). Listening Inventory For Education Questionnaire shoed positive improvements ("highly beneficial)	
Schafer, Wright [14]	To conduct assistive technology evaluations on 12 children diagnosed with ASD to evaluate the potential benefits of remote microphone (RM) technology	**Case study – within subject design** 12 participants who completed the study (age 6 to 17 years) 5 participants did not complete the study due to one or more of the following reasons: 1) the inability to tolerate wearing the RM technology (n = 3) 2) parent and teacher questionnaires were not returned following the trial period, and the child was unable to do behavioural testing (n = 1)	The individual and group teacher (n = 8–9), parent (n = 8–9), and participant (n = 9) questionnaire ratings revealed substantially less listening difficulty when RM technology was used compared to the no-device ratings. Medium to large effect sizes and significant benefit across all questionnaires On the behavioural measures, individual data revealed varied findings (missing data).	**Level: IV** **Quality: Low** (The true effect might be markedly different from the estimated effect) small sample of children across the ASD spectrum, actual use time was not recorded, no control group, certain statements on the questionnaires did not

		3) the child was identified with a profound sensorineural hearing loss during the study (n = 1) Digital Phonak Roger inspiro transmitter synced to bilateral, digital Phonak Focus receivers with SlimTubes and open SlimTip domes <u>Questionnaires and test measures</u> A total of five questionnaires were given to teachers, parents, or participants to complete before and after a six-week trial period with the RM technology. • Listening Inventory for Education-Revised • Children's Auditory Performance Scale • Children's Home Inventory for Listening Difficulties • L.I.F.E.-R Student Version • Short Sensory Profile <u>Behavioural measures</u> Laboratory-based behavioural test measures included speech recognition in noise, auditory comprehension and working memory, and acceptable noise levels.	Variability in the data and the inability of some children to complete the behavioural measures indicates that individualized assistive technology evaluations including functional questionnaires will be necessary to determine if the RM technology will be of benefit to a particular child who has ASD.	directly apply to situations that the child experienced at home or at school Author concludes "it should be noted that the device does not cure children of attention deficits, language disorders, and auditory processing issues."

		Children asked to use system 2 hours per day. Actual use time was not recorded		
van der Kruk, Wilson [15]	Reviews the literature to determine if improving the signal-to-noise ratio (SNR) improves classroom performance in students with ASD	**Systematic Review** Six databases: PubMed, Scopus, Embase, ERIC, CINAHL and PsychInfo. No publication time limit was applied, but publications in languages other than English and/or in non-electronic sources and grey literature were excluded. Participant inclusion criteria: 1) school-aged children ASD with or without other comorbid developmental disorders such as ADD/ ADHD 2) Exposed for any duration to some form of SNR enhancement be that device (e.g. personal FM or soundfield amplification) or environmental (e.g. acoustic treatment of the classroom) in nature.	5 research studies included Limitations of these studies (which have been reviewed above) • Lack of randomized controlled trials • Lack of explicit descriptions of how ASD was diagnosed in participating children • Small sample sizes • Potential participant bias in some questionnaire data • Low teacher response rates • Relatively low number of 'low-functioning' children with ASD. While further research is clearly needed into improving SNR to improve classroom performance in children with ASD, at least two warnings from the studies reviewed here should be heeded.	**Level: IV** (only low level studies included) **Quality: Moderate** (the authors believe that the true effect is probably close to the estimated effect) Sold methods used. Studies included were of low quality which impacts the certainty of results.

			1) Some children with ASD being unable to tolerate the personal FM systems used in. This promotes the need to further investigate other technologies that could increase the signal level in the classroom without challenging the tactile sensitivities found in many students with ASD, such as the soundfield amplification systems 2) The need to include functional outcome measures in studies involving children with ASD (such as video classroom observation, sensory and listening experience-focussed questionnaires, etc) as some of these children will not be able to complete some of the more widely used behavioural outcome measures.	

Table 1. Evidence Regarding Benefit of Remote-Microphone Technology in Children with Normal Hearing and Auditory Differences

Disorder; Participants	Authors, Year	Test Measure: Results
APD: • 10 APD • 13 controls	Johnston et al., 2009	1. Sentence recognition in speech-shaped noise at +5 dB SNR: Improved significantly by 10 dB with FM vs. without FM with greater FM benefit for APD vs. control group 2. Parent SIFTER: At baseline, APD significantly worse than controls for 'Academics', but the difference no longer existed for Academics after the FM trial 3. Participant LIFE: Significant benefit of FM over no FM when teacher talking in front of room, teacher talking with back turned, and other students making noise 4. Psychosocial function BASC-2: Improved ratings for locus of control, anxiety, depression, and interpersonal relationships
ASD: • 10 ASD with FM • 10 controls	Rance et al., 2014	1. Word recognition in babble at 0 dB SNR: Average improvement of 17% from no-FM to FM condition for ASD group and 10% improvement for control group 2. Child APHAB: Significantly less difficulty with communication, in noise, and in reverberation 3. Teacher LIFE: Teachers rated FM as "highly beneficial" for each child; FM improved listening/comprehension, classroom behavior, and general attentiveness
ASD/ADHD: • 7 ASD (2 ADHD; 2 APD) • ADHD (2 APD) • 11 controls	Schafer et al., 2013	1. Sentence recognition in babble, decreasing SNRs: Improved significantly by 6 dB over 2 separate test sessions; performance significantly worse than controls with no-FM, but with FM, performance similar to controls 2. Examiner-observed classroom behavior: Significant improvement of on-task behavior with FM vs. no FM 3. Teacher SIFTER: No significant improvements with FM vs. no FM 4. Teacher CHAPS: Significant improvements for noise, quiet, ideal, auditory memory sequencing, and auditory attention span with FM vs. no FM
ASD, ADHD, LD, or SLI • 12 subjects	Schafer et al., 2014	1. Sentence recognition in babble at -5 dB SNR: Right ear FM, left ear FM and bilateral FM significantly better than no-FM condition by an average of 65 to 86% 2. Listening comprehension in classroom noise at -5 dB SNR: Significant improvement with FM vs. no FM on main idea, details, reasoning, vocabulary, and understanding messages subtests 3. Student LIFE-R (n=8) and CHILD (n=7): Significant benefit of FM at school in classroom situations on LIFE; significant benefit of FM at home when in noise and in social situations on the CHILD 4. Parent CHILD: Significant benefit of FM in quiet, in noise, at a distance, in social situations, and for media
ADHD/ADD: • 31 subjects	Updike, 2006	1. Closed-set word recognition in white noise at +4 dB SNR: Average improvement of 34% with FM over no FM 2. Teacher questionnaires: Significant improvement in attention and listening skills
Friedreich Ataxia: • 10 subjects	Rance, 2010	1. Word recognition in babble at 0 dB SNR: Average improvement of 27% from no-FM to FM condition 2. Child APHAB: Significantly less difficulty with communication, in noise, and in reverberation
Dyslexia: • 38 subjects • 19 used FM • 19 controls with Dyslexia	Hornickel et al., 2012	1. Phonological processing and reading: Significant improvements after 1 year trial with FM while controls had no improvements 2. Auditory brainstem response to stop consonants: FM group had significantly improved neural consistency (i.e., repeatability) relative to the control group, particularly in children who showed the greatest gains in phonological awareness

Note. ADHD=Attention-Deficit Hyperactivity Disorder; APD=Auditory Processing Disorder; ASD=Autism Spectrum Disorder; APHAB=Abbreviated Profile of Hearing Aid Benefit; BASC-2=Behavior Assessment System for Children, 2nd edition; CHAPS=Children's Auditory Performance Scale; FM=frequency modulation system; LIFE=Listening Inventory for Education; LD=language disorders; SIFTER=Screening Instrument for Targeting Educational Risk; SLI=Specific Language Impairment; SNR=signal-to-noise ratio.

References

1. Szymanski CA, Brice PJ, Lam KH, Hotto SA. Deaf Children with Autism Spectrum Disorders. Journal of Autism and Developmental Disorders [Internet]. 2012 2012/10/01; 42(10):[2027-37 pp.]. Available from: https://doi.org/10.1007/s10803-012-1452-9.
2. Beers AN, McBoyle M, Kakande E, Dar Santos RC, Kozak FK. Autism and peripheral hearing loss: A systematic review. International Journal of Pediatric Otorhinolaryngology [Internet]. 2014 2014/01/01/; 78(1):[96-101 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S0165587613005533.
3. Alcántara JI, Cope TE, Cope W, Weisblatt EJ. Auditory temporal-envelope processing in high-functioning children with Autism Spectrum Disorder. Neuropsychologia [Internet]. 2012 2012/06/01/; 50(7):[1235-51 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S0028393212000620.
4. Rance G, Saunders K, Carew P, Johansson M, Tan J. The Use of Listening Devices to Ameliorate Auditory Deficit in Children with Autism. The Journal of Pediatrics [Internet]. 2014 2014/02/01/; 164(2):[352-7 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S0022347613012122.
5. Glaaser DJ. The effects of improved classroom acoustics on the educational performance of students with Attention-Deficit/Hyperactivity Disorder: The Johns Hopkins University; 2008.
6. Johnston KN, John AB, Kreisman NV, Hall JW, Crandell CC, Johnston KN, et al. Multiple benefits of personal FM system use by children with auditory processing disorder (APD). International Journal of Audiology [Internet]. 2009 2009/01/01; 48(6):[371-83 pp.]. Available from: https://doi.org/10.1080/14992020802687516.
7. Keith WJ, Purdy SC. Assistive and Therapeutic Effects of Amplification for Auditory Processing Disorder. Semin Hear [Internet]. 2014 //

29.01.2014; 35(01):[027-38 pp.].
8. Rosenberg GG. Classroom Acoustics and Personal FM Technology in Management of Auditory Processing Disorder. Semin Hear [Internet]. 2002 //

04.12.2002; 23(04):[309-18 pp.].
9. Schafer EC, Mathews L, Mehta S, Hill M, Munoz A, Bishop R, et al. Personal FM systems for children with autism spectrum disorders (ASD) and/or attention-deficit hyperactivity disorder (ADHD): An initial investigation. Journal of Communication Disorders [Internet]. 2013 2013/01/01/; 46(1):[30-52 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S0021992412001165.
10. Schafer EC, Florence S, Anderson C, Dyson J, Wright S, Sanders K, et al. A critical review of remote-microphone technology for children with normal hearing and auditory differences. Journal of Educational Audiology [Internet]. 2014; 20. Available from: http://www.auditorycenter.com/wp-content/uploads/2014/08/Critical-Review-of-Remote-Mic-Technology.pdf.
11. Schafer EC, Traber J, Layden P, Amin A, Sanders K, Bryant D, et al. Use of Wireless Technology for Children with Auditory Processing Disorders, Attention-Deficit Hyperactivity Disorder, and Language Disorders. Semin Hear [Internet]. 2014 //

25.07.2014; 35(03):[193-205 pp.]. Available from: https://www.thieme-connect.com/products/ejournals/abstract/10.1055/s-0034-1383504.
12. Rance G. Journal Club: In Autism Study, FM System Enhances Listening, Attention, and Behavior. The Hearing Journal [Internet]. 2013; 66(7). Available from: https://journals.lww.com/thehearingjournal/Fulltext/2013/07000/Journal_Club___In_Autism_Study,_FM_System_Enhances.5.aspx.
13. Rance G, Chisari D, Saunders K, Rault J-L. Reducing Listening-Related Stress in School-Aged Children with Autism Spectrum Disorder. Journal of Autism and Developmental Disorders [Internet]. 2017 2017/07/01; 47(7):[2010-22 pp.]. Available from: https://doi.org/10.1007/s10803-017-3114-4.

14. Schafer EC, Wright S, Anderson C, Jones J, Pitts K, Bryant D, et al. Assistive technology evaluations: Remote-microphone technology for children with Autism Spectrum Disorder. Journal of Communication Disorders [Internet]. 2016 2016/11/01/; 64:[1-17 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S0021992416301009.
15. van der Kruk Y, Wilson WJ, Palghat K, Downing C, Harper-Hill K, Ashburner J. Improved Signal-to-Noise Ratio and Classroom Performance in Children with Autism Spectrum Disorder: a Systematic Review. Review Journal of Autism and Developmental Disorders [Internet]. 2017 2017/09/01; 4(3):[243-53 pp.]. Available from: https://doi.org/10.1007/s40489-017-0111-7.

Research – Venous Thromboembolism (Deep Vein Thrombosis and Pulmonary Embolism): Evidence Based Treatment

Brief	Evidence Based Treatments for ***Venous Thromboembolism (Deep Vein Thrombosis and Pulmonary Embolism)***
Date	20 January 2021
Requester(s)	Alicia s47F - personal privacy (Senior Technical Advisor (TAB/AAT)
Researcher	Craig s47F - persona (Tactical Research Advisor – TAB/AAT)
Cleared	Jane s47F - personal priva (Research Team Leader - TAB)

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

1 Contents

2 Summary

- ***Venous Thromboembolism*** (VTE) is a disease which includes ***Deep Vein Thrombosis*** (DVT) and ***Pulmonary Embolism*** (PE). DVT and PE are both forms of VTE, but they're not the same condition
- The treatment for DVT depends on its anatomical extent (proximal or distal)
- Initial treatment for DVT are anticoagulation medications used to prevent blood clots
- Severe VTE requires additional invasive/surgical measures

3 Introduction

This document summarizes the evidence based research detailed in the 2019 guidelines produced by the Thrombosis and Haemostasis Society of Australia and New Zealand (THANZ) which aims to promote evidence based optimal management of VTE [1, 2].

In the development of the guidelines, a Venous Thromboembolism (VTE) writing group was established within THANZ and comprised of experts in the field of thromboembolic disorders in Australian and New Zealand. All members undertook a detailed literature review and critically appraised existing evidence on the diagnosis and treatment of VTE. Drafts of evidence-based recommendations, practice points and a background manuscript were developed. The recommendations follow the National Health and Medical Research Council levels of evidence and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to determine the strength of the recommendations [1].

4 What is Venous Thromboembolism (VTE)?

VTE is a chronic and frequently recurrent disease that includes deep vein thrombosis (DVT) and pulmonary embolism (PE). DVT and PE are both forms of VTE, but are not the same thing [3]. It is a potentially preventable disease, however, can result in complications such as post-thrombotic syndrome, pulmonary hypertension, recurrent thrombosis, or death.

In DVT a blood clot usually forms in the deep veins of the calf, thigh, or pelvis which may or may not cause symptoms such as swelling, redness or pain. In some people, clots resolve spontaneously, however there is a risk that some or all of the clot may break away and travel to the lungs, resulting in PE. This can cause respiratory symptoms, heart failure or death [4].

VTE can be fatal if untreated; long term morbidity includes post-thrombotic syndrome (PTS) and pulmonary hypertension. Symptoms of VTE are non-specific, and the diagnosis should actively be sought once considered. A diagnosis of VTE has an impact on subsequent pregnancies, oestrogen use, surgery, life insurance and, occasionally, long-haul travel [5].

VTE is the third most common cardiovascular disease, with an annual incidence of more than 10 million people globally [6]. In Australia, at least 17,000 people develop VTE each year (annual incidence, 0.83 per 1,000 population) [7]. The lifetime risk of VTE is 8%, with 1% of people aged over 80 years experiencing their first VTE. This disease is a major cause of health-related economic loss for patient's and the community (estimated to be $1.7 billion for Australia in 2008) [8].

5 Treatment of Venous Thromboembolism

5.1 Overview

- The spectrum of VTE ranges from distal DVT, which may not require anticoagulation (medications that help prevent blood clots), through to proximal DVT to potentially life-threatening PE requiring additional invasive strategies. The treatment for DVT depends on its anatomical extent: in proximal DVT, thrombus is present in the popliteal (and its trifurcation) or a more proximal vein; in distal DVT, thrombus only occurs in the tibial, peroneal, gastrocnemius and soleal veins [9].

- Anticoagulation is indicated in most cases of VTE because it is highly effective in preventing thrombus extension or recurrence by at least 80% [10].

5.2 Anticoagulant therapy for deep vein thrombosis and pulmonary embolism

- Direct oral anticoagulants (DOACs) and warfarin are equally effective and can be prescribed to most patients. GRADE: Strong; Evidence: High [10, 11].

- DOACs do not require routine monitoring, have no known food interactions and few drug interactions, and are favoured in most instances. However, DOACs should not be used during pregnancy or breastfeeding, in which case low molecular weight heparin is indicated [10].

- Edoxaban and rivaroxaban have been shown to be as efficacious as dalteparin in cancer-related thrombosis, but are associated with an increased risk for major bleeding or clinically relevant non-major bleeding (CRNMB) and, therefore, can be considered when appropriate [12, 13].

- Oral factor Xa inhibitors (eg, apixaban, rivaroxaban) are preferred to dabigatran or warfarin to treat proximal DVT and PE because they do not require parenteral anticoagulation for initiation. GRADE: Strong; Evidence: High [10].

5.2.1 Duration of anticoagulation

5.2.1.1 Proximal deep vein thrombosis and pulmonary embolism

- All patients with proximal DVT and PE should receive anticoagulant therapy for at least 3 months. GRADE: Strong; Evidence: Strong [10].

- Patients whose proximal DVT or PE were provoked by major surgery or major trauma can cease anticoagulation at this time [10].

5.2.1.2 Distal deep vein thrombosis

- Uncertainty exists about the value of anticoagulation for distal DVT. In general, anticoagulation is used for proximal DVT and PE, but serial duplex ultrasound (two duplex ultrasound scans over 2 weeks) is reasonable (GRADE: Strong; Evidence: Moderate), especially if the risk of bleeding is increased. Most distal DVT can be treated for 6 – 12 weeks. GRADE: Strong; Evidence: Moderate [14].

5.2.1.3 Extended anticoagulation for deep vein thrombosis and pulmonary embolism (beyond 3–6 months)

- For patients whose events were unprovoked or associated with transient risk factors (non-surgical), decide whether to stop or to continue with extended anticoagulant therapy after 3 months of anticoagulation. Continuing therapy for longer than 3 months reduces the risk of VTE recurrence during therapy by at least 80% but is associated with a major bleeding risk of < 1% per year. Once anticoagulant therapy is stopped, the risk of recurrence is the same as for patients who cease treatment after 3 – 6months when followed up over time [13].

- Aspirin (100 mg daily) reduces the rate of VTE recurrence to a much lesser extent than oral anticoagulants but is associated with similar rates of bleeding to rivaroxaban 10 mg daily [15, 16]. Therefore, aspirin should be avoided, unless anticoagulation cannot be used. GRADE: Strong; Evidence: High

6 Invasive strategies for VTE management

- Invasive treatment modalities for acute removal of thrombosis have been investigated, with the goals of rapidly relieving acute right ventricular pressure overload in PE and thereby improving survival or rapidly relieving venous obstruction to prevent vein dysfunction and PTS and reduce VTE recurrence [5].

- The following strategies have been investigated with variable results [17-20]:
    - Systemic administration of thrombolytic agents
    - Catheter-directed thrombolysis, which uses lower thrombolytic doses with or without the addition of mechanical clot disruption
    - Acute surgical thrombectomy

7. References

1. Tran HA, Gibbs H, Merriman E, Curnow JL, Young L, Bennett A, et al. The Diagnosis and Management of Venous thromboembolism – Guidelines of the Thrombosis and Haemostasis Society of Australia and New Zealand2019. Available from: https://www.thanz.org.au/documents/item/411.
2. Thrombosis and Haemostasis Society of Australia and New Zealand. About Us 2021 [Available from: https://www.thanz.org.au/about-us/about-us.
3. Healthline. What's the Difference Between Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)? 2021 [Available from: https://www.healthline.com/health/dvt-vs-pulmonary-embolism.
4. Australian Commission on Safety and Quality in Health Care. Venous Thromboembolism Prevention Clinical Care Standard (January 2020)2020. Available from: https://www.safetyandquality.gov.au/sites/default/files/2020-01/venous_thromboembolism_prevention_clinical_care_standard_-_jan_2020_2.pdf.
5. Tran HA, Gibbs H, Merriman E, Curnow JL, Young L, Bennett A, et al. New guidelines from the Thrombosis and Haemostasis Society of Australia and New Zealand for the diagnosis and management of venous thromboembolism. Medical Journal of Australia [Internet]. 2019; 210(5):[227-35 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.5694/mja2.50004.
6. Raskob GE, Angchaisuksiri P, Blanco AN, Buller H, Gallus A, Hunt BJ, et al. Thrombosis. Arteriosclerosis, Thrombosis, and Vascular Biology [Internet]. 2014; 34(11):[2363-71 pp.]. Available from: https://www.ahajournals.org/doi/abs/10.1161/ATVBAHA.114.304488.
7. Ho WK, Hankey GJ, Eikelboom JW. The incidence of venous thromboembolism: a prospective, community-based study in Perth, Western Australia. Medical Journal of Australia [Internet]. 2008; 189(3):[144-7 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.5694/j.1326-5377.2008.tb01947.x.
8. Fletcher J, Baker R, C CF, et al. The burden of venous thromboembolism in Australia. Access Economics [Internet]. 2008. Available from: https://www.safetyandquality.gov.au/wp-content/uploads/2018/10/Access-Economics_The-burden-of-VTE-inAustralia_2008.pdf.
9. PALARETI G, SCHELLONG S. Isolated distal deep vein thrombosis: what we know and what we are doing. Journal of Thrombosis and Haemostasis [Internet]. 2012; 10(1):[11-9 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1538-7836.2011.04564.x.
10. Kearon C, Akl E, Ornelas J, et a. Antithrombotic Therapy for VTE Disease: CHEST Guideline. Chest [Internet]. 2016; 149:[315–52 pp.]. Available from: https://journal.chestnet.org/article/S0012-3692(15)00335-9/fulltext.
11. Pengo V, Denas G, Zoppellaro G, Jose SP, Hoxha A, Ruffatti A, et al. Rivaroxaban vs warfarin in high-risk patients with antiphospholipid syndrome. Blood [Internet]. 2018; 132(13):[1365-71 pp.]. Available from: https://doi.org/10.1182/blood-2018-04-848333.
12. Raskob GE, van Es N, Verhamme P, Carrier M, Di Nisio M, Garcia D, et al. Edoxaban for the Treatment of Cancer-Associated Venous Thromboembolism. New England Journal of Medicine [Internet]. 2017; 378(7):[615-24 pp.]. Available from: https://www.nejm.org/doi/full/10.1056/NEJMoa1711948.
13. Young AM, Marshall A, Thirlwall J, Chapman O, Lokare A, Hill C, et al. Comparison of an Oral Factor Xa Inhibitor With Low Molecular Weight Heparin in Patients With Cancer With Venous Thromboembolism: Results of a Randomized Trial (SELECT-D). Journal of Clinical Oncology [Internet]. 2018; 36(20):[2017-23 pp.]. Available from: https://ascopubs.org/doi/abs/10.1200/JCO.2018.78.8034.
14. Boutitie F, Pinede L, Schulman S, Agnelli G, Raskob G, Julian J, et al. Influence of preceding length of anticoagulant treatment and initial presentation of venous thromboembolism on risk of

recurrence after stopping treatment: analysis of individual participants' data from seven trials. BMJ [Internet]. 2011; 24(342). Available from: https://www.bmj.com/content/342/bmj.d3036.
15. Brighton TA, Eikelboom JW, Mann K, Mister R, Gallus A, Ockelford P, et al. Low-Dose Aspirin for Preventing Recurrent Venous Thromboembolism. New England Journal of Medicine [Internet]. 2012; 367(21):[1979-87 pp.]. Available from: https://www.nejm.org/doi/full/10.1056/NEJMoa1210384.
16. Weitz JI, Lensing AWA, Prins MH, Bauersachs R, Beyer-Westendorf J, Bounameaux H, et al. Rivaroxaban or Aspirin for Extended Treatment of Venous Thromboembolism. New England Journal of Medicine [Internet]. 2017; 376(13):[1211-22 pp.]. Available from: https://www.nejm.org/doi/full/10.1056/NEJMoa1700518.
17. Meyer G, Vicaut E, Danays T, Agnelli G, Becattini C, Beyer-Westendorf J, et al. Fibrinolysis for Patients with Intermediate-Risk Pulmonary Embolism. New England Journal of Medicine [Internet]. 2014; 370(15):[1402-11 pp.]. Available from: https://www.nejm.org/doi/full/10.1056/NEJMoa1302097.
18. Vedantham S, Goldhaber SZ, Julian JA, Kahn SR, Jaff MR, Cohen DJ, et al. Pharmacomechanical Catheter-Directed Thrombolysis for Deep-Vein Thrombosis. New England Journal of Medicine [Internet]. 2017; 377(23):[2240-52 pp.]. Available from: https://www.nejm.org/doi/full/10.1056/NEJMoa1615066.
19. Wan S, Quinlan DJ, Agnelli G, Eikelboom JW. Thrombolysis Compared With Heparin for the Initial Treatment of Pulmonary Embolism. Circulation [Internet]. 2004; 110(6):[744-9 pp.]. Available from: https://www.ahajournals.org/doi/full/10.1161/01.CIR.0000137826.09715.9C.
20. Sharifi M, Bay C, Skrocki L, et al. "MOPETT" Investigators. Moderate pulmonary embolism treated with thrombolysis (from the "MOPETT" trial). Am J Cardiol [Internet]. 2003; 111:[273–7 pp.]. Available from: https://www.ajconline.org/article/S0002-9149(12)02205-9/fulltext.

Research – Bursitis: Evidence Based Treatments

Brief	Evidence based treatments for ***Bursitis.***
Date	January 20, 2021
Requester(s)	Alicia s47F - personal privacy (Senior Technical Advisor (TAB/AAT))
Researcher	Craig s47F - persona (Tactical Research Advisor (TAB?AAT)
Cleared	Jane s47F - personal priva (Research Team Leader (TAB)

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

1 Contents

2 Summary

- Bursitis can often be treated at home, especially if the patient can avoid the activity that might have triggered it
- Most patients respond to nonsurgical management, including ice, activity modification, and nonsteroidal anti-inflammatory drugs
- Treatment will depend on the cause of the bursitis, and aims to relieve the symptoms as much as possible while the healing process takes place
- When a bursa is infected, it is known as "septic bursitis". When not infected it is known as "aseptic bursitis"
- There are four types of bursa each requiring different treatment
- Depending on the type and severity of the bursa, anti-inflammatory medications or injections of corticosteroids may be required, and surgical excision (a definitive option) of the bursal sac may be necessary.

3 What is Bursitis?

Bursitis is an inflammation or irritation of the small, fluid-filled 'cushions' that protect a tendon where it touches a bone. These cushions are called bursae (or bursa (singular) if there's just one).

Muscles in our bodies are connected to the bones via strong white fibrous cords called tendons. Wherever these tendons cross bones and joints, the body creates a small cushion filled with fluid, which is known as a bursa.

When a bursa becomes irritated or inflamed, it swells with fluid and the swelling can be painful and restrict movement [1].

Bursitis must be distinguished from arthritis, fracture, tendinitis, and nerve pathology [2].

When a bursa is infected, it is called septic bursitis. Septic bursitis typically affects bursae located at the knee and elbow joints. Unlike aseptic (non-infectious) bursitis, septic bursitis is a potentially serious medical condition and prompt medical attention is advisable [3].

4 Symptoms of Bursitis

Joint pain can be experienced when the patient moves and is often the first symptom of bursitis. The area may also have swelling, feel warm or look red. As bursitis progresses, the patient might even feel pain when at rest.

The swollen bursa can make the joint stiff and its movement might be restricted [1].

5 Causes of Bursitis

Bursitis is commonly caused by overuse of a joint, especially by doing repetitive movements. The movements might be through work, such as kneeling to clean or garden, or through sport, such as playing tennis.

Bursitis can also be caused by an injury to the joint, and by conditions that cause swelling such as gout and rheumatoid arthritis. It is most common in the knee and shoulder, but also occurs in the hip, elbow, wrist, ankle and heel [1].

6 Types of Bursitis

The Common types of bursitis include [2]:

- Pre-patellar
- Olecranon
- Trochanteric
- Retro-calcaneal

7 Treatment and Management

7.1 Overview

Bursitis can often be treated at home, especially if the patient can avoid the activity that might have triggered it [1].

Treatment will depend on the cause of the bursitis, and aims to relieve the symptoms as much as possible while the healing process takes place. Treatment options may include [4]:

- Pain-relieving medications
- Cold packs
- Gentle mobilising exercises and rest
- Anti-inflammatory medications or injections of corticosteroids may be used in cases of severe pain

Most patients respond to nonsurgical management, including ice, activity modification, and nonsteroidal anti-inflammatory drugs [2].

If infection is present, as well as pain and swelling of the affected area, other symptoms may develop, such as a raised temperature. Treatment with an appropriate antibiotic is necessary [4].

If the bursitis was triggered by a particular form of overuse, it‘s important to avoid that activity, or modify how you perform that activity. An occupational therapist can help you find solutions to this problem [4].

7.2 Pre-patellar Bursitis

Bursitis arises from many inflammatory phenomena, but infection is the primary concern. Approximately 80% of cases of septic pre-patellar bursitis are caused by Staphylococcus aureus.

Local corticosteroid injection may be used in the management of pre-patellar bursitis.

Management of septic pre-patellar bursitis is controversial. Recommendations range from oral antibiotics alone to surgical excision of the bursal sac. The primary decision in developing a treatment algorithm is whether to initiate nonsurgical or surgical management. Most patients respond to nonsurgical treatment. Surgery is a definitive option that is associated with complications. Management of aseptic pre-patellar bursitis typically consists of rest, compression, and nonsteroidal anti-inflammatory drugs (NSAIDs). It may also include local corticosteroid injection [2, 5].

7.3 Olecranon Bursitis

Olecranon bursitis is the most common superficial bursitis [2, 6]. Fluid collection within and inflammation around the bursa are caused by traumatic, inflammatory, and infectious processes. Olecranon bursitis is typically non-infectious in origin; septic bursitis accounts for approximately 20% of all acute cases [2, 7].

Management of olecranon bursitis is dictated by its aetiology. Acute traumatic or idiopathic olecranon bursitis typically resolves with nonsurgical management. Ice, compressive dressings, and avoidance of aggravating activity are sufficient in most patients [2, 8]. When a patient does not improve as expected, aspiration should be performed to rule out infection. Alternatively, in the patient in whom fluid collection is bothersome at presentation, aspiration with or without concurrent corticosteroid injection may be done [2, 9]. In a study of 47 patients with traumatic bursitis who underwent aspiration, 90% recovered in 6 months [2, 10]. Intrabursal corticosteroid injection is associated with complications, including infection, skin atrophy, and chronic pain [2, 10].

7.4 Trochanteric Bursitis

Patients with trochanteric bursitis typically present with lateral hip pain, which may radiate to the buttock, groin, or low back. Symptoms may be exacerbated by ambulation, walking uphill, stair climbing, and rising from a seated position [2].

Initial management consists of physical therapy and oral NSAIDs. If symptoms persist, local glucocorticoid injection is performed [2, 11, 12]. Most patients respond to nonsurgical management [2].

7.5 Retrocalcaneal Bursitis

Inflammation of the retrocalcaneal bursa can limit function and cause pain. The Achilles tendon and its bony insertion may be involved in severe cases. This spectrum of disease has been given many names, including Haglund syndrome, Albert disease, calcaneus altus, pump bump, winter heel, and achillodynia [13].

Management of these causes of posterior heel pain begins with ice, activity modification, NSAIDs, and orthoses. Shoe wear modification to prevent irritation of the posterior heel by the shoe counter should be considered, as well. Manoeuvres that stretch the local Achilles tendon may aid in attenuating the symptoms [2].

Surgical intervention is warranted for retrocalcaneal bursitis that does not resolve with nonsurgical management. Accurate clinical diagnosis guides surgical management. For refractory cases associated with Haglund deformity, open procedures include resection of the calcaneal prominence proximal to the Achilles insertion, debridement of Achilles tendinopathy, and complete excision of the retrocalcaneal bursa [14-16]. Alternatively, dorsal closing wedge osteotomy may be considered to rotate the posterior calcaneus to a lesser prominence [17]. Complications of open procedures include skin breakdown, Achilles tendon avulsion, altered sensation, and painful scar formation [2, 13, 18].

8 References

1. Healthdirect. Bursitis 2021 [Available from: https://www.healthdirect.gov.au/bursitis.
2. Daniel LA, Amar P, Stephen K, Ryan C. Four Common Types of Bursitis: Diagnosis and Management. J Am Acad Orthop Surg [Internet]. 2011; 19(6):[359-67 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/21628647/.
3. Arthritis Health. Septic Bursitis 2019 [Available from: https://www.arthritis-health.com/types/bursitis/septic-bursitis.
4. Better Health Channel. Bursitis: Department of Health & Human Services: State Government of Victoria; 2020 [Available from: https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/bursitis.
5. Langford CA, BC G. Periarticular disorders of the extremities, in Fauci AS, Braunwald E, Kasper DL, et al, eds: Harrison's Principles of Internal Medicine, 17e.
6. Pien FD, Ching D, Kim E. Septic bursitis : experience in a community practice. Orthopedics [Internet]. 1991; 14(9):[981-4 pp.]. Available from: https://europepmc.org/article/med/1946062.
7. Jaffe L and Fetto JF. Olecranon bursitis. Contemp Orthop1984.
8. J J Canoso. Idiopathic or traumatic olecranon bursitis. Clinical features and bursal fluid analysis. Arthritis Rheum [Internet]. 1977; 20(6):[1213-6 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/901595/.
9. BF Morrey. (in) The Elbow and its Disorders (ed 4). Philadelphia: Saunders; 2009. p. 1164-73.
10. Weinstein PS, Canoso JJ, Wohlgethan JR. Long-term follow-up of corticosteroid injection for traumatic olecranon bursitis. Annals of the rheumatic diseases [Internet]. 1984; 43(1):[44-6 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/6696516/.
11. M I Shbeeb 1 and E L Matteson. Trochanteric bursitis (greater trochanter pain syndrome). Mayo Clin Proc [Internet]. 1996; 71(6):[565-9 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/8642885/.

12. Schapira D, Nahir M, Scharf Y. Trochanteric bursitis: a common clinical problem. Arch Phys Med Rehabil [Internet]. 1986; 67(11):[815-7 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/3778178/.
13. Leitze Z, Sella, Enzo, Aversa, John. Endoscopic Decompression of the Retrocalcaneal Space. J Bone Joint Surg Am [Internet]. 2003 18/01/21; 85(8):[1488-96 pp.]. Available from: http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=ovftf&NEWS=N&AN=00004623-200308000-00009.
14. P Angermann. Chronic retrocalcaneal bursitis treated by resection of the calcaneus. Foot Ankle [Internet]. 1990; 10(5):[285-7 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/2341100/.
15. Pauker M, Katz K, Yosipovitch Z. Calcaneal ostectomy for Haglund disease. Foot Surg [Internet]. 1992; 31(6):[588-9 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/1469219/.
16. Schneider W, Niehus W, Knahr K. Haglund's syndrome: disappointing results following surgery -- a clinical and radiographic analysis. Foot Ankle Int [Internet]. 2000; 21(1):[26-30 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/10710258/.
17. AE Miller and TA Vogel. Haglund's deformity and the Keck and Kelly osteotomy: a retrospective analysis. J Foot Surg [Internet]. 1989; 28(1):[23-9 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/2654263/.
18. Ortmann FW, McBryde AM. Endoscopic bony and soft-tissue decompression of the retrocalcaneal space for the treatment of Haglund deformity and retrocalcaneal bursitis. Foot & ankle international [Internet]. 2007; 28(2):[149-53 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/17296130/.

Research – Degenerative Lumbar Disc Disease (DLDD): Evidence Based Treatments

Brief	Evidence based treatments for ***Degenerative Lumbar Disc Disease***
Date	19 January 2021
Requester(s)	Alicia s47F - personal privacy (Senior Technical Advisor (TAB/AAT)
Researcher	Craig s47F - perso r (Tactical Research Advisor – TAB/AAT)
Cleared	Jane s47F - personal priv (Research Team Leader - TAB)

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

1 Contents

2 Summary

- There are many evidence based treatment options available which encompass non-pharmacological, pharmacological, and surgical treatments
- There appears to be no superior treatment/intervention
- Treatment is based on best evidence, physician experience and patient preference
- Treatment encompasses a multidisciplinary/multimodal approach

3 What is Degenerative Lumbar Disc Disease (DLDD)?

DLDD is a chronic degenerative condition of the lumbar spine that affects the vertebral bodies and intervertebral discs of the low back. The discs lose water content and shrink, and spurs often form as osteoarthritis develops.

Lumbar degenerative disc disease is quite common and progresses with age. The condition can cause lumbar spinal stenosis [1].

4 Symptoms

Many people do not have symptoms, but symptoms can occur at any time. Typical symptoms include pain or stiffness of the back.

If the canal around the nerves narrows, patients can experience:

- Back pain
- Leg pain
- Numbness, tingling or weakness of the legs
- Difficulty with walking and lack of balance or coordination

- Occasionally, bowel and bladder control problems may occur [1]

5 Treatment

5.1 Overview

There are many treatment options available to the clinician. No treatment has been shown to be superior, and multimodal therapy is the cornerstone of treatment. The individualisation of treatment is based on best evidence, physician experience and patient preference [2].

Australia currently has no clinical care guidelines, however they are in development [3]. Various overseas evidence based guidelines are used within Australia including those researched by the University of South Australia [4].

A recent 2020 research article published in the Australian Journal of General Practice [2] aims to assist Australian clinicians assess patients with Lower Back Pain (LBP) and formulate evidence-based treatment decisions. The article outlined first, second, and third lines of treatment. The lines of treatment encompass three treatment groups; non-pharmacological, pharmacological, and surgery.

5.2 First-line treatment

- Education
- Early return to activity
- Weight loss
- Exercise/physiotherapy
- Nonsteroidal anti-inflammatory drugs
- Tai chi/yoga/Pilates
- Paracetamol
- Acupuncture

5.3 Second-line treatment

- Multidisciplinary rehabilitation
- Psychological therapy
- Antidepressants
- Injections – facet/epidural

5.4 Third-line treatment

- Tapentadol (an opioid pain medication)

- Surgery

5.5 Non-pharmacological

5.5.1 Education

- Patient education regarding aetiology, prognosis and treatment options is paramount for treating LBP. Prognosis is favourable with long-term treatment programs focusing on symptomatic relief. Educational material may be individually useful but has not been shown to improve outcomes [5].

- Cold packs can be used in the acute inflammation phase, while hot packs can be used in the chronic muscle spasm phase. Massage can improve pain, depression and sleep in the medium term [6].

5.5.2 Exercise/Physiotherapy

- It is recommended that activity modification be done in phases. A period of light activity and avoidance of painful activities is appropriate for several days. However, bed rest is not recommended [7].

- An early return to low-stress aerobic activity and work improves pain tolerance, mood and strength in chronic LBP [8].

- Physiotherapy-directed strengthening and posture control can start after the acute period and continue indefinitely. Core exercises are more effective than general exercise for decreasing pain and increasing function [9].

5.5.3 Weight Loss

- It is important to emphasise long-term weight reduction, with a loss of ≥5% body weight reducing the prevalence of LBP [10]. Given the low-risk profile of the above treatments, they can be beneficial for all patients.

5.5.4 Psychological therapy

- Psychological therapy, such as cognitive behaviour therapy and progressive relaxation, has been shown to result in a moderate improvement in pain [10, 11].

5.5.5 Multidisciplinary rehabilitation

- Multidisciplinary rehabilitation combines psychological therapy, physical therapy, occupational therapy and social work. A systematic review of 41 trials of patients with LBP for longer than three months found rehabilitation improves pain and disability in the short- and long-term when compared with usual treatment [12]. This can be considered for patients with difficult-to-treat chronic LBP.

5.5.6 Acupuncture and Chiropractic

- Acupuncture and chiropractic and spinal manipulation are treatments that differ greatly in how they are performed, making effectiveness difficult to assess. A systematic review found acupuncture superior to placebo in the short term [13]. There was no reliable difference in pain or function when compared with active conventional treatment for chronic LBP. Adverse effects are often mild and transitory, such as bleeding, swelling or light-headedness. Acupuncture can be considered as part of a treatment regimen at the patient's request.

- Chiropractic interventions do not appear to be beneficial for chronic LBP when compared with standard treatment [13]. A systematic review found a small benefit for spinal manipulation when compared with placebo, but it is not superior to conventional treatment [14]. Given the rare but catastrophic risk from disc herniation leading to cauda equina syndrome (1:1 million), caution should be exercised before recommending spinal manipulation.

5.5.7 Orthoses

- No reliable evidence is available to support the routine use of orthoses, braces, corsets, prolotherapy or magnets in LBP [15].

5.6 Pharmacological

5.6.1 Paracetamol

- Paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), muscle relaxants and antidepressants can be used to treat LBP because of their low-risk profile [2].

- Paracetamol is a relatively safe medication for mild-to-moderate chronic LBP. However, paracetamol does not appear to be beneficial for patient with acute LBP when used in isolation. A Cochrane review showed that NSAIDs are more effective than placebo for reducing pain and disability without increased adverse events [16].

- While there is no difference in efficacy between NSAIDs, cyclooxygenase-2 (COX-2) inhibitors are effective and have fewer side effects when compared with traditional NSAIDs [2].

- Tramadol and tapentadol are opiate-like medications that can be used cautiously in patients with severe LBP. A systematic review of tramadol found mild improvement in short-term pain and function when compared with placebo [17]. Recent review articles have suggested that tapentadol is safe and efficacious in the treatment of chronic LBP [18, 19].

- It is recommended that opiate medication be used sparingly and only for acute, difficult-to-control pain. It is associated with serious adverse effects, drug misuse, dependency and variable efficacy. A large meta-analysis of 20 randomised controlled trials examined the effects of opiates on chronic LBP [20].

5.6.2 Antidepressants

Antidepressants can be used in cases of chronic LBP. A systemic review showed reduced pain but no difference in global outcome with antidepressants when compared with placebo [17]. Efficacy is improved if the patient has concomitant depression. Tricyclic antidepressants appear to work better than serotonin reuptake inhibitors [21].

5.7 Surgery

Surgery for LBP can be considered for patients who have unremitting pain and functional limitation for >1 year. Patients should maximise a comprehensive non-operative treatment regimen. Motion-preserving disc arthroplasty theoretically reduces stress and subsequent degeneration at adjacent levels. However, spinal degeneration is most commonly treated with a fusion procedure. This can be achieved by laying a bone graft posterolaterally or in the disc space, with or without instrumentation. Interbody fusion involves fusing the disc space from the front (anterior lumbar interbody fusion), side (oblique or direct lateral lumbar interbody fusion) or posterior (posterolateral or transforaminal interbody fusion). Studies have reported varied clinical success rates from 40% to 90% [22, 23]. Inconsistent results may be due to variable surgical indications, pathologies and surgical treatments. Patient selection is paramount for improving clinical outcomes [2].

6 References

1. University of Michigan: Comprehensive Musculoskeletal Centre. Lumbar Degenerative Disease 2021 [Available from: https://www.uofmhealth.org/conditions-treatments/cmc/back-neck-and-spine-conditions/lumbar-degenerative-disease.
2. A Parr and G Askin. Non-radicular low back pain: Assessment and evidence-based treatment. Australian Journal of General Practice [Internet]. 2020. Available from: https://www1.racgp.org.au/ajgp/2020/november/non-radicular-low-back-pain.

3. Australian Commission on Safety and Quality in Health Care. Low Back Pain Clinical Care Standard 2019 [Available from: https://www.safetyandquality.gov.au/standards/clinical-care-standards/low-back-pain-clinical-care-standard.
4. University of South Australia: International Centre for Allied Health Evidence. Low Back Pain Guidelines 2020 [Available from: https://www.unisa.edu.au/research/Health-Research/Research/Allied-Health-Evidence/Resources/GuidelineCH/Low-Back-Pain-Guidelines/.
5. Cherkin DC, Deyo RA, Street JH, Hunt M, Barlow W. Pitfalls of patient education: limited success of a program for back pain in primary care. Spine [Internet]. 1996; 21(3):[345-55 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/8742212/.
6. Cherkin DC, Sherman KJ, Deyo RA, Shekelle PG. A review of the evidence for the effectiveness, safety, and cost of acupuncture, massage therapy, and spinal manipulation for back pain 2003 [898-906]. Available from: https://www.acpjournals.org/doi/abs/10.7326/0003-4819-138-11-200306030-00011.
7. Hagen KB, Hilde G, Jamtvedt G, Winnem MF. The Cochrane review of bed rest for acute low back pain and sciatica. Spine [Internet]. 2000; 25(22):[2932-9 pp.]. Available from: https://journals.lww.com/spinejournal/Abstract/2000/11150/The_Cochrane_Review_of_Bed_Rest_for_Acute_Low_Back.16.aspx.
8. van Tulder MW, Malmivaara A, Esmail R, Koes BW. Exercise therapy for low-back pain. Cochrane Database of Systematic Reviews [Internet]. 2000; (2). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000335/full.
9. Coulombe BJ, Games KE, Neil ER, Eberman LE. Core stability exercise versus general exercise for chronic low back pain. Journal of athletic training [Internet]. 2017; 52(1):[71-2 pp.]. Available from: https://meridian.allenpress.com/jat/article/52/1/71/111614/Core-Stability-Exercise-Versus-General-Exercise.
10. Dunlevy C, MacLellan GA, O'Malley E, Blake C, Breen C, Gaynor K, et al. Does changing weight change pain? Retrospective data analysis from a national multidisciplinary weight management service. European Journal of Pain [Internet]. 2019; 23(8):[1403-15 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/ejp.1397.
11. Chou R, Huffman LH. Nonpharmacologic therapies for acute and chronic low back pain: a review of the evidence for an American Pain Society/American College of Physicians clinical practice guideline. Annals of internal medicine [Internet]. 2007; 147(7):[492-504 pp.]. Available from: https://www.acpjournals.org/doi/full/10.7326/0003-4819-147-7-200710020-00007.
12. Abbey H. Multidisciplinary biopsychosocial rehabilitation for chronic low back pain: Cochrane systematic review and meta-analysis. International Journal of Osteopathic Medicine [Internet]. 2015; 18(3):[239-40 pp.]. Available from: https://www.journalofosteopathicmedicine.com/article/S1746-0689(15)00082-6/abstract.
13. Walker BF, French SD, Grant W, Green S. A Cochrane review of combined chiropractic interventions for low-back pain. Spine [Internet]. 2011; 36(3):[230-42 pp.]. Available from: https://journals.lww.com/spinejournal/Abstract/2011/02010/A_Cochrane_Review_of_Combined_Chiropractic.8.aspx.
14. Rubinstein S, Zoete Ad, Middelkoop Mv, Assendelft W, Boer Md, Tulder Mv. Benefits and harms of spinal manipulative therapy for the treatment of chronic low back pain: systematic review and meta-analysis of randomised controlled trials. BMJ [Internet]. 2019; 364:l689. Available from: https://www.bmj.com/content/364/bmj.l689.
15. Jellema P, Tulder Mv, Poppel Mv, Nachemson A, Bouter L. Lumbar supports for prevention and treatment of low back pain: a systematic review within the framework of the Cochrane Back Review Group. Spine [Internet]. 1976. Available from: https://pubmed.ncbi.nlm.nih.gov/11224885/.
16. Enthoven WT, Roelofs PD, Deyo RA, van Tulder MW, Koes BW. Non-steroidal anti-inflammatory drugs for chronic low back pain. Cochrane Database of Systematic Reviews [Internet]. 2016; (2). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD012087/abstract.

17. Chung J, Zeng Y, Wong T. Drug therapy for the treatment of chronic nonspecific low back pain: systematic review and meta-analysis. Pain physician [Internet]. 2013; 16(6):[E685-E704 pp.]. Available from: https://www.researchgate.net/profile/Ying_Zeng7/publication/258957913_Drug_Therapy_for_the_Treatment_of_Chronic_Nonspecific_Low_Back_Pain_Systematic_Review_and_Meta-analysis/links/5587e7b808aeb0cdade0ec04/Drug-Therapy-for-the-Treatment-of-Chronic-Nonspecific-Low-Back-Pain-Systematic-Review-and-Meta-analysis.pdf.
18. Coluzzi F, Polati E, Freo U, Grilli M. Tapentadol: an effective option for the treatment of back pain. Journal of pain research [Internet]. 2019; 12:[1521 p.]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6526923/.
19. Pergolizzi JV, Taylor R, LeQuang JA, Raffa RB, Bisney J. Tapentadol extended release in the treatment of severe chronic low back pain and osteoarthritis pain. Pain and therapy [Internet]. 2018; 7(1):[37-57 pp.]. Available from: https://link.springer.com/article/10.1007/s40122-018-0095-8.
20. Shaheed CA, Maher CG, Williams KA, Day R, McLachlan AJ. Efficacy, tolerability, and dose-dependent effects of opioid analgesics for low back pain: a systematic review and meta-analysis. JAMA internal medicine [Internet]. 2016; 176(7):[958-68 pp.]. Available from: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2522397.
21. Staiger TO, Gaster B, Sullivan MD, Deyo RA. Systematic review of antidepressants in the treatment of chronic low back pain. Spine [Internet]. 2003; 28(22):[2540-5 pp.]. Available from: https://journals.lww.com/spinejournal/Abstract/2003/11150/Systematic_Review_of_Antidepressants_in_the.14.aspx.
22. Colhoun E, McCall I, Williams L, Pullicino VC. Provocation discography as a guide to planning operations on the spine. J Bone Joint Surg Br [Internet]. 1988; 70(2):[267-71 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/2964449/.
23. Linson M, Williams H. Anterior and combined anteroposterior fusion for lumbar disc pain: A preliminary study. Spine [Internet]. 1976; 16(2):[143-5 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/1707187/.

Research – Osteoporosis: Evidence Based Treatments

Brief	Evidence Based Treatments for ***Osteoporosis***
Date	21 January 2021
Requester(s)	Alicia s47F - personal privacy (Senior Technical Advisor (TAB/AAT)
Researcher	Craig s47F - persona (Tactical Research Advisor – TAB/AAT)
Cleared	Jane s47F - personal priva (Research Team Leader - TAB)

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

1 Contents

2 Summary

- Treatment for osteoporosis is based on bone health maintenance and the prevention of fracture
- Treatment for osteoporosis is largely pharmacological where pharmacological interventions prevent further bone loss and reduce fracture risk
- Treatment decisions should be based on age, sex, medical history, severity of the condition and estimated absolute risk of fracture [1]
- Most current osteoporosis medications are anti-resorptive, and reduce the natural but excessive process of bone loss [1]
- Other agents increase the formation of new bone; these are most appropriate for more severe osteoporosis, especially if a patient is unresponsive to anti-resorptive therapy [1]
- Osteoporosis medicines are grouped into different 'classes' depending on their 'active ingredient' [2]:
    - Bisphosphonates (tablets)
    - Denosumab (injection)
    - Selective oestrogen receptor modulators (SERMS) (tablet)
    - Hormone replacement therapy (HRT) (tablets)
    - Teriparatide (injection)
- Management of Osteoporosis includes diet and lifestyle, education and psychosocial support, and supplementing calcium and vitamin D.

3 Introduction

This document summarizes the latest evidence based research detailed in the guideline produced by the Royal Australian College of General Practitioners (RACGP) and Osteoporosis Australia in 2017 [1].

The guideline is designed to provide clear, evidence-based recommendations to assist general practitioners and other health professionals in managing older patients with osteoporosis. The purpose of the guideline is to support clinical judgement.

The majority of the recommendations in the guideline are based on critical analysis of the body of published, peer-reviewed evidence that has accumulated from September 2006 to February 2016, following a systematic review of the available evidence to support the recommendations. Where insufficient evidence was available, or where the quality of the evidence did not meet minimum requirements set by the RACGP research working group, recommendations were developed through working group consensus.

4 What is Osteoporosis?

Osteoporosis is a condition where bones become thin, weak and fragile, such that even a minor bump or accident can cause a broken bone (minimal trauma fracture). It is most common in older women, affecting over 1 in 4 aged over 75. The hip was the most common site for minimal trauma fractures (32% of fractures). In 2017–18 there were 93,321 hospitalisations for minimal trauma fractures in people aged 50 and over. An estimated 924,000 Australians have osteoporosis, representing 3.8% of the population [3].

Osteoporosis is characterised by both low bone mineral density (BMD) and micro-architectural deterioration of bone tissue, leading to decreased bone strength, increased bone fragility and a consequent increase in fracture risk. BMD is usually reported as a T-score, the number of standard deviations (SDs) of the BMD measurement above or below that of young healthy adults of the same sex. Approximately 50% of first or subsequent minimal trauma fractures occur in people who have T scores in the normal or osteopenic range [1].

5 Treatment and management of osteoporosis recommendations

5.1 General bone health maintenance and fracture prevention

5.1.1 Diet and lifestyle

Promote the following important lifestyle choices for all postmenopausal women and men over 50 years of age:

- Adequate calcium and protein intake
- Adequate but safe exposure to sunlight as a source of vitamin D
- Maintenance of a healthy weight and body mass index
- Cessation of smoking
- Avoidance of excessive alcohol consumption

5.1.2 Education and psychosocial support

- Provide postmenopausal women and men over 50 years of age at risk of or diagnosed with osteoporosis, access to education, psychosocial support and encouragement to seek support from appropriate sources according to individual needs

5.1.3 Reducing the risk of falls

- Conduct falls risk assessments and initiate targeted fall-prevention programs in older adults

5.1.4 Exercise

- Individuals over 50 years of age without osteoporosis should participate regularly in progressive resistance training and balance training exercises. Resistance exercise should be regular (2–3 days per week), moderate–vigorous, progressive and varied to influence BMD and reduce fall and fracture risk

- Prescribe high-intensity progressive resistance and balance training to older adults with osteoporosis to prevent further bone loss and/or improve BMD, improve function, treat sarcopenia, and decrease fall and fracture risk.

- Prescribe extended exercise therapy, including resistance and balance training, after hip fracture to improve mobility, strength and physical performance. Evidence for the benefits of exercise after vertebral and non-hip fractures is limited.

5.1.5 Calcium and vitamin D supplementation

- Calcium and vitamin D supplements should not be used routinely in noninstitutionalised elderly people. The absolute benefit of calcium and vitamin D supplements in terms of fracture reduction is low. There is evidence of significant benefit in people at risk of deficiency, particularly institutionalised individuals. Calcium and vitamin D supplements should be offered to people taking osteoporosis treatments if their dietary calcium intake is less than 1300 mg per day.

5.2 Pharmacologic approaches to prevention and treatment

5.2.1 Bisphosphonates

- Bisphosphonate therapy should be considered for the primary prevention of vertebral fractures in women with osteopenia who are at least 10 years post menopause.
- Bisphosphonate therapy (alendronate, risedronate or zoledronic acid) is recommended for reducing the risk of vertebral and non-vertebral fractures in postmenopausal women and men over 50 years of age at high risk of fracture (those with osteoporosis by BMD criteria or a prior minimal trauma fracture)
- Reconsider the need to continue bisphosphonate therapy after 5–10 years in postmenopausal women and men over 50 years of age with osteoporosis who have responded well to treatment (T-score ≥–2.5 and no recent fractures). If BMD remains low (T-score ≤–2.5) and/or there are incident vertebral fractures, continue treatment. Treatment should be restarted if there is evidence of bone loss, especially at the hip, or if a further minimal trauma fracture is sustained.

5.2.2 Denosumab

- Denosumab is recommended for the treatment of osteoporosis in postmenopausal women at increased risk of minimal trauma fracture.
- Denosumab should be considered as an alternative to bisphosphonates for the treatment of men at increased risk of minimal trauma fracture.

5.2.3 Hormone therapy

- Consider oestrogen replacement therapy to reduce the risk of fractures in postmenopausal women. The increase in risk of adverse events associated with treatment should be weighed carefully against benefits. Long-term use is not recommended.
- Selective oestrogen receptor modulators (SERMs) should be considered as a treatment option for postmenopausal women with osteoporosis where vertebral fractures are considered to be the major osteoporosis risk (on the basis of low spine BMD and/or an existing vertebral fracture) and where other agents are poorly tolerated. SERMs may be particularly useful in younger postmenopausal women at risk of vertebral fracture and who have a prior or family history of breast cancer.

5.2.4 Parathyroid hormone

- Teriparatide treatment is recommended to reduce fracture risk in postmenopausal women and men over 50 years of age with osteoporosis who have sustained a subsequent fracture while on anti-resorptive therapy, or in whom anti-resorptive therapy is contraindicated.

5.2.5 Strontium ranelate

- Strontium ranelate at a dose of 2 g per day is an effective second-line option for reducing the risk of further osteoporotic fractures in postmenopausal women with prevalent fractures. Strontium ranelate should not be used in patients with previous or clinically active cardiovascular disease or uncontrolled hypertension and should only be used when other medications for the treatment of osteoporosis are unsuitable.

5.3 Ongoing monitoring

- Regularly re-assess fracture risk and requirement for anti-osteoporotic therapy in patients who are not receiving therapy, but remain at increased risk of fracture.

- Review all patients 3–6 months after initiating a specific pharmacological intervention for osteoporosis, and annually thereafter. BMD testing at the 3–6 month review is not indicated.

- Biochemical markers of bone turnover should not be routinely used for the diagnosis of osteoporosis in general practice. Measurement of markers should be confined to specialist practice, and may be useful for the monitoring of adherence to treatment and in the evaluation of secondary causes of bone loss.

5.4 Special issues

5.4.1 Management of osteoporosis in the elderly

- Calcium and vitamin D supplementation is recommended for the prevention of fracture in the frail elderly and institutionalised elderly. Optimisation of calcium and vitamin D should be the standard of care for this group.

- Consider the use of hip protectors to reduce the risk of hip fracture in residential-care settings, but not in community settings.

- Anti-resorptive therapy is recommended for reduction of fracture risk in people over 75 years of age with osteoporosis.

- Anabolic therapy with teriparatide may be considered for reduction of vertebral fracture risk in people over 75 years of age with osteoporosis.

- Multifactorial assessment of falls risk, exercise programs and home-safety interventions are recommended to reduce the rate of falls in community dwelling people over 75 years of age.

- Vitamin D supplementation of elderly people in care facilities is recommended to reduce the rate of falls. Vitamin D supplements given for falls prevention are normally combined with calcium to address the high rates of calcium deficiency also seen in this population.

- Evidence-based exercise modalities that progress in intensity as capacity improves are recommended for the maintenance of bone strength, muscle function and balance in people over the age of 75.

- Exercise programs for very frail elderly institutionalised people and those with vertebral fracture risk should be supervised, modified and tailored to minimise the potential to increase the risk of falls, injury and vertebral fractures.

5.4.2 Aromatase inhibitor and androgen deprivation therapy

- All women undergoing aromatase inhibitor (AI) therapy should have a baseline assessment of fracture risk prior to commencing therapy.

- Women undergoing AI therapy who fall within one of the following two categories should commence anti-resorptive therapy unless contraindicated:

    - 70 years or over with a BMD T-score ≤–2.5
    - 50 years or over with a minimal trauma fracture (including radiological vertebral fracture) or a high estimated 10-year risk of fracture. There is limited evidence specific to women receiving AI to guide firm recommendations outside these criteria, especially in premenopausal women.

- The duration of anti-resorptive treatment in women who are undergoing or have completed AI therapy should be individualised and based on absolute fracture risk.

- General measures to prevent bone loss should be implemented in all women commencing AI therapy.

- All men commencing androgen deprivation therapy (ADT) should have a baseline assessment of fracture risk. BMD by DXA should be measured in all patients at the time of commencement of ADT.

- All men receiving ADT who have a history of minimal trauma fracture should be commenced on anti-resorptive therapy, unless contraindicated.
- Management of bone health should be reviewed 1–2 yearly in men on continuous ADT.
- General measures to prevent bone loss should be implemented in all men commencing ADT.

6 References

1. The Royal Australian College of General Practitioners and Osteoporosis Australia. Osteoporosis prevention, diagnosis and management in postmenopausal women and men over 50 years of age (2nd ed.)2017. Available from: https://www.racgp.org.au/getattachment/2261965f-112a-47e3-b7f9-cecb9dc4fe9f/Osteoporosis-prevention-diagnosis-and-management-in-postmenopausal-women-and-men-over-50-years-of-age.aspx.
2. Osteoporosis Australia. Treatment Options 2014 [Available from: https://www.osteoporosis.org.au/treatment-options.
3. Australian Institute of Health Welfare. Osteoporosis2020. Available from: https://www.aihw.gov.au/reports/chronic-musculoskeletal-conditions/osteoporosis.

Research – Osteoarthritis (OA): Evidence Based Treatments

Brief	Evidence based treatments for ***Osteoarthritis (OA).***
Date	January 18, 2021
Requester(s)	Alicia s47F - personal privacy (Senior Technical Advisor (TAB/AAT))
Researcher	Craig s47F - persona (Tactical Research Advisor (TAB?AAT)
Cleared	Jane s47F - personal priv (Research Team Leader (TAB)

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

1 Contents

2 Summary

- This document makes substantial use of the following comprehensive research paper: Arthritis Australia. Evidence to support the national strategic action plan for arthritis, 2019.
- A range of evidence-based national and international guidelines and standards of care have been developed to support the timely and effective management of OA
- Evidence based first line treatment strategies for OA involve weight loss, exercise, patient education and self-management support, where a multidisciplinary management approach is taken.
- A variety of medications are used to support OA to increase bone mineral density, manage symptoms such as pain and inflammation, and reduce the risk of fractures.
- Complementary medicines are often used in conjunction with pharmaceuticals or as an alternative to traditional medicines
- Joint replacement surgery is used for severe, symptomatic OA, when first line treatment options fail.
- Although devices such as braces, walking sticks, and shoe insoles, are often utilized in OA treatment, there appears to be little evidence of their effectiveness.

3 What is Osteoarthritis (OA)?

Osteoarthritis (OA) is a chronic condition characterised by the breakdown of the cartilage that overlies the ends of bones in joints. This results in the bones rubbing together, causing pain, swelling and loss of motion. OA usually gets worse over time and commonly affects the hands, spine and joints such as hips, knees and ankles [1].

OA has no specific cause, however several factors contribute to the onset and progression [2], including:

- being female
- genetic factors
- excess weight
- joint misalignment
- joint injury or trauma (such as dislocation or fracture)
- repetitive joint-loading tasks (for example, kneeling, squatting and heavy lifting).

OA is the most common form of arthritis in Australia. An estimated 2.2 million (9.3%) Australians have this condition, according to the Australian Bureau of Statistics (ABS) 2017–18 National Health Survey. OA represented over half (62%) of all arthritic conditions in 2017–18 [1, 3].

Although OA affects people of all ages, the prevalence increases sharply from the age of 45 years. 1 in 5 Australians (22%) over the age of 45 have OA. It is most common in adults aged 75 and over, with just over one-third (36%) of people in this age group experiencing the condition [1, 3].

OA is also more common among females than males, affecting 10% of females compared with 6.1% of males (after adjusting for age) [1, 3].

At present, there is no cure for OA and the disease is long-term and progressive. Treatment for OA aims to manage symptoms, increase mobility and maximise quality of life. Treatment options for OA include [4]:

- physical activity
- weight management
- medication
- joint replacement surgery

4 Management and Treatment of OA

4.1 Evidence based Guidelines and Standards of Care

A range of evidence-based national and international guidelines and standards of care have been developed to support the timely and effective management of OA, and particularly, hip and knee OA. These guidelines consistently emphasise that core management of OA should comprise a combination of non-pharmacological and pharmacological interventions, with referral for consideration of surgery only if symptoms are no longer responsive to conservative management [5-13]. The core recommendations for OA management across these guidelines can be broadly summarised as:

- Diagnosis should be based on clinical assessment alone.
- An individualised self-management plan should be developed based on a comprehensive assessment of symptoms, other health conditions and a psychosocial evaluation.
- Conservative (non-surgical) management involving weight loss, exercise, disease-relevant patient education and self-management support are **first-line treatment strategies** and are also recommended at all stages of the disease.
- If required, pharmacological therapies should be added to the core treatments.
- Patients should be included in shared decision-making for the development of a personalized pain management program involving treatment options such as exercise, orthotics, psychological and social interventions, sleep interventions, weight management and pharmacological treatments [8]
- Referral for consideration of surgery should be made only when conservative management no longer provides adequate pain relief or maintenance of function.

4.2 Evidence based Models of Care

Models of care are evidence- and consultation-based frameworks that describe what and how health services and other resources should be delivered to people with specific health conditions. Models of care aim to guide the provision of 'the right care, delivered at the right time, by the right team in the right place, with the right resources.' They provide an effective way to embed evidence into health policy and practice and achieve system efficiencies [11, 14].

A number of arthritis-related models of care already exist in some jurisdictions in Australia and are at various stages of implementation. These models have been developed by state-based musculoskeletal clinical networks, which have been identified as an important enabler for the development and implementation of models of care [15]. These models include:

- NSW ACI Osteoarthritis Chronic Care Program (OACCP) Model of Care
- NSW ACI Local Musculoskeletal Service (LMS)
- Osteoarthritis of the Hip and Knee Service (Victoria)
- Victorian Model of Care for Osteoarthritis of the Knee and Hip
- WA Inflammatory Arthritis Model of Care
- WA Service Model for Community-Based Musculoskeletal Health • WA Elective Joint Replacement Service Model of Care
- Model of Care for NSW Paediatric Rheumatology Network
- Orthopaedic Physiotherapy Screening Clinic and Multidisciplinary Service (Queensland)
- Comprehensive Osteoarthritis Pathway and Musculoskeletal Triage and Assessment Service (Tasmania).

4.3 Treatment and Interventions

4.3.1 Overview

Treatments for OA include:

- Weight Loss
- Exercise
- Pain Management using medication
- Devices such as braces, walking sticks, and shoe insoles
- Surgery, if symptoms are no longer controlled with other therapies

Weight loss, exercise, and a multidisciplinary approach to both, are viewed as conservative treatments and interventions. Surgery is regarded as non-conservative [11].

4.3.2 Weight Loss

- For **obese people with established OA**, weight loss of between 5-10% of their body weight can result in significant pain relief, and this may in turn manifest in improvements in

mobility, physical function and quality of life [16]. Weight loss greater than 10% achieves even larger improvements in symptoms [17].

- Strategies to support weight loss in people with OA may include informal advice, referral to a dietician for appropriate counselling and structured weight loss programs incorporating dietary changes and/or exercise [18].

4.3.3 Exercise

- There is a large body of evidence in support of exercise for OA, with exercise achieving improvements in knee pain and physical function comparable to those reported from non-steroidal anti-inflammatory drugs [19]. Improvements in pain and function following exercise programs for hip OA have also been shown [20].

- **Therapeutic water-based exercise** has also been shown to have benefits for patients with lower limb (hip or knee) OA [21].

- **Supported self-management** and exercise programmes, delivered by health professionals, are feasible in clinical practice and can positively impact symptoms, function and medication use [22-24].

- **Information, clear advice about benefits and reassurance** from health professionals can encourage greater exercise participation by patients with OA [25].

- Studies of innovative service delivery models for the provision of physiotherapist-supervised exercise management for people with knee OA have found that the use of **Skype and telephone coaching** is feasible and beneficial [26, 27].

- Use of **booster sessions with a physiotherapist** can also help improve exercise adherence for older adults with OA and/or back pain [28].

- Specific **neuromuscular exercise programs** delivered by trained physiotherapists have demonstrated both short and long term improvements in pain, function and quality of life [23].

4.3.4 Multidisciplinary Approach

- Multidisciplinary conservative care programs for OA have been shown to reduce willingness for joint replacement surgery. Most recently, a randomised controlled trial to investigate the effectiveness of total knee replacement plus non-surgical treatments in comparison to nonsurgical interventions alone, found that both groups reported significant improvements in pain, health related quality of life and functional outcomes. Although improvements were greater in the group undergoing joint replacement, two out of three patients eligible for

total knee replacement who received non-surgical treatment, had still not proceeded to surgery at the two-year follow up [29].

4.3.5 Medication

- Pharmaceutical medicines are normally used in the management of osteoporosis to increase bone mineral density, manage symptoms such as pain and inflammation, and reduce the risk of fractures. The most common pharmaceuticals used for this condition are **bisphosphonates, analgesics and synthetic hormones**. [30]

- Medicines used to manage arthritis and osteoporosis can be administered in many different shapes and forms. There are topical treatments and ointments used to alleviate inflammation and mild pain, tablets (often the most common) either to modify the symptoms (for example, analgesics) or the disease (for example, bisphosphonates), and injections which are administered directly into the affected joints to lubricate them or to slow disease progression. Types of medications used for arthritis and osteoporosis [30]:

    - Non-steroidal anti-inflammatory drugs, or NSAIDs, are used to relieve symptoms of pain, stiffness and inflammation in the muscles, joints and bones. NSAIDs can be selective or non-selective and are commonly used to manage arthritis. Medications within this group include celecoxib, meloxicam, ibuprofen, diclofenac and naproxen.

    - Anti-resorptives are a type of medication commonly used in osteoporosis. This group of medicines binds to bone to stop the removal of calcium, assisting in restoring bone density. Common medicines from this group include bisphosphonates such as alendronate, risedronate and other medications like strontium ranelate.

    - Analgesics are medications that relieve pain. These types of medications are used to relieve the symptoms of mild, moderate and severe pain. Common medications used to manage arthritis and osteoporosis include paracetamol, tramadol and paracetamol combinations.

- Typically, treatment is limited to the use of analgesic and/or anti-inflammatory medications to manage symptoms until the condition worsens, at which point the patient is referred for a joint replacement [11].

- There is evidence to support a variety of pharmacological treatment options for pain management. Opioids are generally considered of limited use for managing arthritis pain because the clinical benefits appear to be limited, but the risk of adverse events is high [31, 32].

4.3.6 Devices such as braces, walking sticks, and shoe insoles

Although literature on treatments for OA advise devices such as braces, walking sticks, and shoe insoles, these are not given evidence-based recommendations by national and international guidelines and standards of care.

In 2018 the Royal Australian College of General Practitioners (RCGP) produced the "Guideline for the management of knee and hip osteoarthritis", with the objective to present the best available, current scientific evidence for OA interventions, covering all interventions other than joint replacement for the hip and knee [13].

With regard to devices such as braces, walking sticks, and shoe insoles, the RCGP either do not recommend their use or are unable to recommend either for or against their use. This is based on low or very low quality of evidence in their research.

4.3.7 Surgery

- Joint replacement surgery is a highly effective and cost-effective intervention for OA when conservative therapies are no longer effective. Hip and knee replacements provide substantial and sustained improvements in pain, physical function and quality of life [33].

- Despite the demonstrated effectiveness of joint replacement surgery, not all patients experience optimal outcomes and, as with all surgical procedures there is a risk of complications. A substantial proportion of patients is unsatisfied or continues to experience persistent pain after total hip replacement (6-27%) and total knee replacement (15-44%) [34, 35].

- As joint replacement prostheses have a limited lifespan, future revision surgery may also be required. In view of these considerations, national and international clinical guidelines recommend that joint replacement surgery should only be offered for severe, symptomatic OA after conservative management strategies have been trialled [36, 37].

5 Complementary and Alternative Treatment

- Complementary medicines are often used in conjunction with pharmaceuticals or as an alternative to traditional medicines. In recent years, evidence-based research regarding the use of complementary medicines has gained more momentum [30].

- Clinical trials for glucosamine and omega 3 for OA have indicated that these medications may be effective in reducing pain, inflammation and stiffness [38, 39]. However there are contradictions between research findings and methodologies that call into question whether these medications are truly effective in controlling the symptoms of OA [39].

- Statistically, the ABS, National Health Survey: Summary of Results, 2004-05, indicates that complementary medicines were the most common type of medication to be reported for OA. Females were more likely to be report usage than males overall (48% compared to 36%), with the most common complementary medicines used to manage OA being glucosamine (25%) and fish oils/omega 3 (16%) [40].

6 References

1. Australian Institute of Health Welfare. What is osteoarthritis? Canberra: AIHW; 2020 [Available from: https://www.aihw.gov.au/reports/chronic-musculoskeletal-conditions/osteoarthritis.
2. Kay Chapman AMV. Genetic factors in OA pathogenesis: Bone; 2012 [Volume 51, Issue 2,:[Available from: https://www.sciencedirect.com/science/article/abs/pii/S8756328211013652?via%3Dihub.
3. Commonwealth of Australia. National Health Survey: First results:Reference period 2017-18 financial year 2020 [Available from: https://www.abs.gov.au/statistics/health/health-conditions-and-risks/national-health-survey-first-results/latest-release.
4. Australian Institute of Health Welfare. Osteoarthritis Canberra: AIHW; 2020 [14/01/21]. Available from: https://www.aihw.gov.au/reports/chronic-musculoskeletal-conditions/osteoarthritis.
5. Australian Commission on Safety Quality in Health Care. Osteoarthritis of the knee clinical care standard: Australian Commission on Safety and Quality in Health Care Sydney; 2017 [Available from: https://www.safetyandquality.gov.au/standards/clinical-care-standards/osteoarthritis-knee-clinical-care-standard.
6. Briggs AM, Page CJ, Shaw BR, Bendrups A, Philip K, Cary B, et al. A model of care for osteoarthritis of the hip and knee: development of a system-wide plan for the health sector in Victoria, Australia 2018 [47]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7008674/.
7. Fernandes L, Hagen KB, Bijlsma JW, Andreassen O, Christensen P, Conaghan PG, et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis 2013 [1125-35]. Available from: https://ard.bmj.com/content/72/7/1125?papetoc=&itm_campaign=ard&itm_content=consumer&itm_medium=cpc&itm_source=trendmd&itm_term=0-A.
8. Geenen R, Overman CL, Christensen R, Åsenlöf P, Capela S, Huisinga KL, et al. EULAR recommendations for the health professional's approach to pain management in inflammatory arthritis and osteoarthritis. Annals of the rheumatic diseases. 2018;77(6):797-807.
9. Hochberg MC, Altman RD, April KT, Benkhalti M, Guyatt G, McGowan J, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee 2012 [465-74]. Available from: https://onlinelibrary.wiley.com/doi/full/10.1002/acr.21596.
10. Stoffer MA, Smolen JS, Woolf A, Ambrozic A, Berghea F, Boonen A, et al. Development of patient-centred standards of care for osteoarthritis in Europe: the eumusc. net-project. Annals of the Rheumatic Diseases. 2015;74(6):1145-9.
11. Arthritis Australia. Evidence to support the national strategic action plan for arthritis 2019 [Available from: https://arthritisaustralia.com.au/wordpress/wp-content/uploads/2019/06/190612-Final_Evidence-to-Support-the-NSAPA_Word-Refs.pdf.
12. McAlindon TE, Bannuru RR, Sullivan M, Arden N, Berenbaum F, Bierma-Zeinstra S, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis and

cartilage [Internet]. 2014; 22(3):[363-88 pp.]. Available from: https://www.sciencedirect.com/science/article/pii/S1063458414000168.
13. The Royal Australian College of General Practitioners. Guideline for the management of knee and hip osteoarthritis 2018 [2nd:[Available from: https://www.racgp.org.au/download/Documents/Guidelines/Musculoskeletal/guideline-for-the-management-of-knee-and-hip-oa-2nd-edition.pdf.
14. Briggs AM, Towler SC, Speerin R, March LM. Models of care for musculoskeletal health in Australia: now more than ever to drive evidence into health policy and practice 2014 [401-5]. Available from: https://www.aci.health.nsw.gov.au/__data/assets/pdf_file/0009/255996/Briggs_et_al_2014_Aust_Health_Rev_MSK_MoC_published.pdf.
15. Briggs AM, Bragge P, Slater H, Chan M, Towler SC. Applying a Health Network approach to translate evidence-informed policy into practice: a review and case study on musculoskeletal health 2012 [394]. Available from: https://link.springer.com/article/10.1186/1472-6963-12-394.
16. Bliddal H, Leeds A, Christensen R. Osteoarthritis, obesity and weight loss: evidence, hypotheses and horizons–a scoping review. Obesity reviews [Internet]. 2014; 15(7):[578-86 pp.]. Available from: https://onlinelibrary.wiley.com/doi/10.1111/obr.12173.
17. Messier SP, Resnik AE, Beavers DP, Mihalko SL, Miller GD, Nicklas BJ, et al. Intentional weight loss in overweight and obese patients with knee osteoarthritis: is more better? Arthritis care & research [Internet]. 2018; 70(11):[1569-75 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/acr.23608.
18. Brosseau L, Wells GA, Tugwell P, Egan M, Dubouloz C-J, Casimiro L, et al. Ottawa Panel evidence-based clinical practice guidelines for the management of osteoarthritis in adults who are obese or overweight. Physical therapy [Internet]. 2011; 91(6):[843-61 pp.]. Available from: https://academic.oup.com/ptj/article/91/6/843/2735000?login=true.
19. Fransen M, McConnell S, Harmer AR, Van der Esch M, Simic M, Bennell KL. Exercise for osteoarthritis of the knee. Cochrane database of systematic reviews [Internet]. 2015; (1). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004376.pub3/full.
20. Fransen M, McConnell S, Hernandez-Molina G, Reichenbach S. Exercise for osteoarthritis of the hip. Cochrane Database of Systematic Reviews [Internet]. 2014; (4). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007912.pub2/full.
21. Waller B, Ogonowska-Slodownik A, Vitor M, Lambeck J, Daly D, Kujala UM, et al. Effect of therapeutic aquatic exercise on symptoms and function associated with lower limb osteoarthritis: systematic review with meta-analysis. Physical therapy [Internet]. 2014; 94(10):[1383-95 pp.]. Available from: https://academic.oup.com/ptj/article/94/10/1383/2735524?login=true.
22. Dziedzic K, Healey E, Porcheret M, Afolabi E, Lewis M, Morden A, et al. Implementing core NICE guidelines for osteoarthritis in primary care with a model consultation (MOSAICS): a cluster randomised controlled trial. Osteoarthritis and cartilage [Internet]. 2018; 26(1):[43-53 pp.]. Available from: https://www.sciencedirect.com/science/article/pii/S106345841731244X.
23. Skou ST, Roos EM. Good Life with osteoArthritis in Denmark (GLA: D™): evidence-based education and supervised neuromuscular exercise delivered by certified physiotherapists nationwide. BMC musculoskeletal disorders [Internet]. 2017; 18(1):[1-13 pp.]. Available from: https://bmcmusculoskeletdisord.biomedcentral.com/articles/10.1186/s12891-017-1439-y.
24. Thorstensson CA, Garellick G, Rystedt H, Dahlberg LE. Better management of patients with osteoarthritis: development and nationwide implementation of an evidence-based supported osteoarthritis self-management programme. Musculoskeletal care [Internet]. 2015; 13(2):[67-75 pp.]. Available from: https://onlinelibrary.wiley.com/doi/full/10.1002/msc.1085.
25. Hurley M, Dickson K, Hallett R, Grant R, Hauari H, Walsh N, et al. Exercise interventions and patient beliefs for people with hip, knee or hip and knee osteoarthritis: a mixed methods review. Cochrane database of systematic reviews [Internet]. 2018; (4). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010842.pub2/full.

26. Hinman R, Nelligan R, Bennell K, Delany C. “Sounds a bit crazy, but it was almost more personal:” a qualitative study of patient and clinician experiences of physical therapist–prescribed exercise for knee osteoarthritis via Skype. Arthritis care & research [Internet]. 2017; 69(12):[1834-44 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/acr.23218.
27. Hinman RS, Delany CM, Campbell PK, Gale J, Bennell KL. Physical therapists, telephone coaches, and patients with knee osteoarthritis: qualitative study about working together to promote exercise adherence. Physical Therapy [Internet]. 2016; 96(4):[479-93 pp.]. Available from: https://academic.oup.com/ptj/article/96/4/479/2686489.
28. Nicolson PJ, Bennell KL, Dobson FL, Van Ginckel A, Holden MA, Hinman RS. Interventions to increase adherence to therapeutic exercise in older adults with low back pain and/or hip/knee osteoarthritis: a systematic review and meta-analysis. British journal of sports medicine [Internet]. 2017; 51(10):[791-9 pp.]. Available from: https://bjsm.bmj.com/content/51/10/791.short.
29. Skou ST, Roos EM, Laursen MB, Rathleff MS, Arendt-Nielsen L, Rasmussen S, et al. Total knee replacement and non-surgical treatment of knee osteoarthritis: 2-year outcome from two parallel randomized controlled trials. Osteoarthritis and cartilage [Internet]. 2018; 26(9):[1170-80 pp.]. Available from: https://www.sciencedirect.com/science/article/pii/S1063458418312214.
30. Australian Institute of Health and Welfare. Medication use for arthritis and osteoporosis Canberra: AIHW; 2010 [Available from: https://www.aihw.gov.au/reports/chronic-musculoskeletal-conditions/medication-use-arthritis-osteoporosis.
31. da Costa BR, Nüesch E, Kasteler R, Husni E, Welch V, Rutjes AW, et al. Oral or transdermal opioids for osteoarthritis of the knee or hip. Cochrane Database of Systematic Reviews [Internet]. 2014; (9). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003115.pub4/full.
32. Whittle SL, Richards BL, Husni E, Buchbinder R. Opioid therapy for treating rheumatoid arthritis pain. Cochrane Database of Systematic Reviews [Internet]. 2011; (11). Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003113.pub3/full.
33. Shan L, Shan B, Suzuki A, Nouh F, Saxena A. Intermediate and long-term quality of life after total knee replacement: a systematic review and meta-analysis. JBJS [Internet]. 2015; 97(2):[156-68 pp.]. Available from: https://journals.lww.com/jbjsjournal/Abstract/2015/01210/Intermediate_and_Long_Term_Quality_of_Life_After.10.aspx.
34. Beswick AD, Wylde V, Gooberman-Hill R, Blom A, Dieppe P. What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients. BMJ open [Internet]. 2012; 2(1). Available from: https://bmjopen.bmj.com/content/2/1/e000435.short.
35. Wylde V, Hewlett S, Learmonth ID, Dieppe P. Persistent pain after joint replacement: prevalence, sensory qualities, and postoperative determinants. PAIN® [Internet]. 2011; 152(3):[566-72 pp.]. Available from: https://www.sciencedirect.com/science/article/abs/pii/S0304395910007086.
36. Harris M, Bennett J, Del Mar CB, Fasher M, Foreman L, Furler J, et al. Guidelines for preventive activities in general practice: The Royal Australian College of General Practitioners; 2009.
37. National Institute for Health and Clinical Excellence Ocam. Osteoarthritis: care and management clinical guideline 2014 [Available from: www.nice.org.uk/guidance/cg177/resources/osteoarthritis-careand-management-35109757272517.
38. Goldberg RJ, Katz J. A meta-analysis of the analgesic effects of omega-3 polyunsaturated fatty acid supplementation for inflammatory joint pain. Pain [Internet]. 2007; 129(1-2):[210-23 pp.]. Available from: https://www.sciencedirect.com/science/article/abs/pii/S0304395907000413.
39. McAlindon TE, LaValley MP, Gulin JP, Felson DT. Glucosamine and chondroitin for treatment of osteoarthritis: a systematic quality assessment and meta-analysis. Jama [Internet]. 2000; 283(11):[1469-75 pp.]. Available from: https://jamanetwork.com/journals/jama/article-abstract/192498.

40. Australian Bureau of Statistics. National Health Survey: Summary of Results, 2004-05 2006 [Available from: https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/4364.02004-05.

Research – Factors affecting plan budget and utilisation

Brief	IA project- addressing historical biases in planning to control for these variables and identify supports that should be funded. The Tune review and review of data by the OSA indicates a number of factors, such as location and socioeconomic factors impact the size and utilisation of NDIS Plan budgets (greater disadvantage = lower plan and lower plan utilisation). Requesting a broad review of the literature to identify known factors which impede service utilisation. Identified factors for TAB to provide a short commentary of impact and options for remediation: CALD ATSI Multiple participants in the family "thin market" Regional/remote/very remote Education status Health/services literacy
Date	06/05/2021
Requester(s)	Katrin s47F - personal p – Assistant Director (TAB)
Researcher	Jane s47F - personal priv - Research Team Leader (TAB)
Cleared	N/A

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

1 Contents

2 Culturally and Linguistically Diverse Populations

A study by Zhou [1] has found that the rate of access of specialist disability services by people with disability who were from culturally and linguistically diverse (CALD) backgrounds is **highly disproportionate to their presence in the community.**

As a whole, people from CALD backgrounds:

- Have a similar level of disability as Australia-born people.
- Have a greater rate of profound and severe disability.
- A higher level of need for assistance in undertaking core activities.

For younger age cohorts targeted by specialist disability services, there is little difference in the level of need for assistance between people from CALD backgrounds and the rest of community. Those people who mainly speak languages other than English at home have a relatively higher level of need for assistance than those who speak mainly English at home.

2.1 Barriers and impact

- Some cultures tend to offer more informal care to their community and family members than others [1, 2].
- Literacy and language skills, including lack of understanding about disability (at an individual level and by parents of children with a disability).
- The need for an interpreter.
- Lack of knowledge about what government funded services exist in Australia. Particularly those who come from cultures where states provide very limited support to people with disability. Although multilingual information is available, this cohort may not proactively search for services.
- Cultural competence of service providers.

2.2 Potential responses

- Recognition that this service access gap exists.
- Narrowing the gap requires better understanding (research) of how cultural characteristics of people with disability from CALD backgrounds impact their access.
- Effectively disseminate service information targeting people with language barriers of the existence of services.

3 Aboriginal and Torres Strait Islander Communities

The Australian Institute of Health and Welfare (AIHW) reports that the prevalence of disability is more than twice as high in Aboriginal and Torres Strait Islander populations [3]. Among the Aboriginal and Torres Strait Islander population there are higher rates of young people caring for people with disabilities and higher rates of people with intellectual and psychological disabilities involved in the criminal justice system [4]. Participation rates of Indigenous people in disability services are lower than the reported prevalence of disability [4].

Many Indigenous people see trauma and loss of their cultural lands and sacred sites as constituting significant disabilities [5]. Disability is also seen to arise as a result of a lack of Western education, such as the inability to read or do arithmetic, and the difficulty in getting past the barriers of discrimination to access government and non-government-managed services [5]. Furthermore, disability is commonly accepted as just part of life and supporting people with disabilities is seen as family business [5].

Although not disability specific, the 2014-2015 Aboriginal and Torres Strait Islander Health Survey conducted by the Department of the Prime Minister and Cabinet found that 35% of respondents believed they had been treated unfairly within the previous 12 months because they were an Aboriginal or Torres Strait Islander person [6]. Of those, 13% reported they had avoided seeking healthcare due to experiencing unfair treatment in the past [6]. It is highly likely that these trends also occur in the disability sector.

3.1 Barriers and impact

Aboriginal and Torres Strait Islander people are not sufficiently involved in planning, delivering and evaluating relevant services [4].

- Lack of facilities that provide culturally appropriate services
- Lack of information regarding services available
- Negative attitudes of providers (perceptions of racism, blame and disregard or culture)
- Social marginalisation
- Remoteness
- Child care
- Transportation
- Mistrust in government services and agencies.
- Cultural attitudes, shame and stigma [5, 7]
    - Categorisation on the basis of perceived abilities or disabilities is seen as another attempt to erode their social solidarity.
    - Discussing a person's physical impairments can bring shame and embarrassment to the person and to his or her family.
    - Family roles often function as a barrier for the provision of disability services because offering help and assistance to Indigenous people with disabilities can be misinterpreted as an embarrassment and an insult to the competence of their family.
- Transience of non-Indigenous people in very remote areas makes it very difficult for them to form the support networks that are needed to assist with the raising of a child with disability.

3.2 Potential responses

- Empower Aboriginal and Torres Strait Islander people and their communities to develop and implement new engagement strategies [4].
- Development of an Indigenous definition of disability that captures the diversity of cultures and experiences of colonisation among the Indigenous population [5].
- Increase the cultural competency of service providers [5].
- Development of a conceptual framework for research and policy development regarding Indigenous people with disabilities, each Indigenous community must be understood in the context of their experience of colonisation, disadvantage and cultural heritage [5].

The study by DiGiacomo, Delaney [8] provides a table of carer and providers suggestions to address barriers to access.

Solution Categories	Carer-preferred solutions	Provider solutions

Aboriginal Community Controlled Health Service-based support	• Provide education, workshops, information sessions, and support groups (especially for children with intellectual disability) for families. • Opportunities for carers to speak with health professionals/ service providers face-to-face (rather than computer or phone). • Collect accurate data on number of children in the community with disabilities to inform local and government strategies.	• Grassroots-based; educating families and teachers on disability and available services; focus on prevention. • Work within a family-centred, flexible model, personal approach, and holistic approach.
Aboriginal Child Disability Support Workers	• Need for a dedicated support worker/ Aboriginal Child Disability Worker with disability expertise - role in care navigation, health education, interpretation of medical jargon and liaison support with services.	• Work within a centralised, case manager model; explore other effective and acceptable models (including funding models) in urban Aboriginal populations.
Increased flexibility	• Increased flexibility and responsiveness of respite services.	• Minimise red-tape and rigid criteria, particularly during crisis; increase flexibility for Aboriginal families.
School-based support	• Utilise school data on Indigenous and disability status to ensure adequate resource distribution; facilitate linkages between other support agencies and schools.	• Increase awareness of disability and support available across professions and within communities; increase opportunity for network building across sectors.
Contact Information	• Routinely updated listing of services and contacts for support (general and disability-specific information; with consideration for child's developmental stages).	
Inter-sectoral partnerships	• Partnerships between schools, parents, and community controlled organisations were also seen as strategies to enable access to services.	

4 Multiple participants in the family

Statistics from the United States indicate that approximately 21% of households with children with disabilities had multiple disabled children [9]. However, not much is known about the characteristics of households who have multiple children with disabilities and their experiences.

One important limitation of the existing caregiving research is its exclusive focus on one focal child with disabilities in households [9]. In instances where families have multiple children with disabilities, researchers often randomly choose one child for analysis or might select the child with a more severe condition, ignoring any other children with disabilities in the household [9].

4.1 Barriers and impact

Various reports have found that households with more than one child with a disability are [9-11]:

- More likely to be single parents.
- Lack of support system/informal supports.
- Less likely to be in work.
- High levels of stress and poor mental health.
- Negative social status.
- More likely to be in semi-skilled or unskilled manual jobs.
- More likely to be dependent on income support.
- Less likely to own their own home.
- Markedly higher rates of income poverty.
- Greater unmet needs at all income levels.
- Higher prevalence of disabled adults in the household.
- Time spent on the coordination of care for each individual child is significant
    - increased direct and indirect costs to these families

4.2 Potential responses

- Expanding support (beyond the current level) for low income households raising multiple children with disabilities [9].
- Providers and professionals should anticipate that families raising multiple children with disabilities likely experience significantly elevated rates of hardship and deprivation. They need to assist these families to efficiently co-ordinate care for multiple children with disabilities and secure all available support services and entitlements [9].

5 "Thin Market"

Thin markets exist where there is a gap between the needs of participants and the services available in the market. The persistence of thin markets can constrain the agency's ability to deliver reasonable and necessary supports.

The below barriers, impact and potential responses were taken from the thin markets discussion paper commissioned by the Commonwealth Department of Social Services and the NDIS [12].

5.1 Barriers and impact

- Geographic isolation: Physical distance and travel time results in higher costs for service delivery for isolated or highly dispersed communities
- Vulnerable clients: The communities that some providers serve may have complex and higher needs including isolation, complex disability, support needs and challenges in self-determining their need. These clients require more highly qualified staff to service their needs.
- Higher operating costs: Low client numbers (or difficulty in finding/connecting with clients that are in the region), and/or highly dispersed clients result in higher per client costs than can be supported under existing NDIS staff utilisation.
- Workforce: Challenges in recruiting and retaining qualified workforces and providing learning and development opportunities.
- Temporary supply gaps: Some supports (such as certain specialist's supports and allied health services) take time to reach levels required to meet demand.

5.2 Potential responses

Market Facilitation: These responses seek to enable competitive markets, for example by giving participants information about the service options or providers available to them, or matching supply and demand through electronic platforms. Supply partnerships, such as place-based collaborative models, alternative business models, co-operatives or sharing infrastructure between providers, can also support providers to overcome their service delivery challenges.

- Examples that fall under this approach include the facilitation or provision of e-markets platforms (e.g. my Aged Care), or programs that aim to facilitate the growth or transition of the sector (e.g. the Sector Development Fund).

Market Deepening: These responses seek to encourage supply to meet needs, including by 'bundling' together demand for different services to enhance efficiency, where supplying one of the services is inefficient; by pooling individualised funding to ensure economies of scale for a provider; or by stimulating or providing direct supply inputs, such as by encouraging skilled workers into markets in need.

- Examples that fall under this approach include the mechanism used in the Multipurpose Services model to bundle aged care, disability and health services, or programs that encourage skilled workers to move to regional or remote areas (e.g. the Bonded Medical Places Scheme, or the National Rural Health Student Network)

Regulation: These responses may control market operation to varying degrees through regulating or setting prices, controlling market access, or otherwise governing the operation of the markets to ensure it achieves service objectives.

- Examples that fall under this approach include: adding or modifying regional loadings within the regulated price regime (e.g. changes accepted as part of the Independent Pricing Review); or selection of service providers who can deliver services within certain catchments.

Alternative commissioning models (incl. community led responses): This includes options that involve direct commissioning or government provision of services, for example regulated monopoly (one service provider) or oligopoly (few service providers) models. Options would also include commissioning of community led responses (whether or not the financing would come from government).

- Examples that would fall under this approach include: directly contracting with a provider, or number of providers, to provide access to services; or providing seed funding for a community-led partnership.

6 Regional/remote/very remote

The burdensome effects of disability are amplified by the degree of remoteness. Unfortunately, those who live outside of metropolitan areas become victims of circumstance.

6.1 Barriers and impact

- Contrast in quality and availability of disability support services between the major cities and rural and remote areas
- Lack of capacity in over-stretched towns to deal with disability
- Lack of and prescriptive nature of respite services
- Lack of suitable alternative activities for people with disability
- Transport
    - Lack of availability of public transport in some rural and remote areas
    - Greater costs incurred by people with disability in travelling to consultations
    - Increased time expended by health professionals in delivering services in rural and remote areas compared with metropolitan areas.

6.2 Potential responses

The National Rural Health Alliance and National Disability and Carer Alliance have provided some solutions to the above issues [13].

Tele-practice

- Tele-practice is a therapy service that is delivered in-part or in-whole via remote telecommunication. This may comprise elements including (but not limited to) Skype, video sharing, instant messaging, email, and telephone.

- Tele-practice can eliminate travel time, and increase choice in service providers outside the local area.

Allied Health Assistants

- Allied health assistants (AHAs) are certificate-qualified individuals who can implement interventions under the guidance of an allied health professional, remotely or in-person.
- AHAs can have an in-depth knowledge of local community needs at the same time as having a broad knowledge of allied health services.
- The combination of an AHA and clinician brings expertise in the local community, and expertise in clinical practice, as well as providing a more regular and timely service to individuals, since the clinician need not be physically present at all times.

Fly-in-fly-out practitioners

- FIFO allied health practitioners who specialise in disability have the potential to empower rural and remote communities, and build capacity amongst generalist allied health practitioners, educators, and allied health assistants.

7 Education status

The AIHW states that:

- 21% of people aged 16-64 who acquired disability before age 15 left school before 16 (8.9% without disability).
- 34% of people aged 20 and over with disability have completed year 12 (66% without disability).
- 17% of people aged 20 and over with disability have a bachelor's degree or higher (35% without disability).

Level of education attained can affect participation in other key life areas, including employment, ability to achieve economic independence or the skills to manage adult life (following school).

7.1 Barriers and impact

- Some schools can create barriers to education for children with a disability. Lack of educational attainment impacts the participant and society.
- Lack of an assertive family member/informal support network to advocate on the behalf of the participant can make it difficult to navigate the system.
    - Mild intellectual disability may be a barrier to reaching out and obtaining support.

7.2 Potential responses

Lack of any suggestions in this area. Allocation of an advocate for participants with a lack of understanding of how to navigate the NDIS and find services/providers. More frequent check-ins with high risk participants.

8 Health/services literacy

Individual health literacy is the skills, knowledge, motivation and capacity of a person to access, understand, appraise and apply information to make effective decisions about health and health care and take appropriate action. Health literacy is important because it shapes people's health and the safety and quality of health care [14].

8.1 Barriers and impact

Some of the different people who may be at higher risk of low individual health literacy include [14]:

- People from lower socio-economic backgrounds.
- People with lived mental health experience
- Elderly people
- People living with disabilities
- Aboriginal and Torres Strait Islander peoples
- People from CALD backgrounds
- People with drug and alcohol dependencies
- People experiencing chronic or complex illness
- People who are homeless, socially isolated or geographically isolated.

- Lack of knowledge impacts the decisions made and actions of participants at home, in the workplace and the community.
- Health literacy influences people's lifestyle choices, the type of preventive health actions they take and the way they access, use and maintain healthcare regimens.
    - can exacerbate underlying access and equity issues that people from disadvantaged groups may be experiencing
- A person with a disability may have difficulties with physical access to health services, or have difficulty communicating with healthcare providers which is a barrier to participating in their own health care.

8.2 Potential responses

To address health literacy in a coordinated way in Australia it's necessary to:

- Embed health literacy into high-level systems and organisational policies and practices.
- Ensure that health information is clear, focused and useable.
- Integrate health literacy into education for consumers and healthcare providers.

9 References

1. Zhou Q. Accessing disability services by people from culturally and linguistically diverse backgrounds in Australia. Disability and Rehabilitation [Internet]. 2016 2016/04/23; 38(9):[844-52 pp.]. Available from: https://doi.org/10.3109/09638288.2015.1062925.
2. Boughtwood D, Shanley C, Adams J, Santalucia Y, Kyriazopoulos H, Pond D, et al. Culturally and Linguistically Diverse (CALD) Families Dealing with Dementia: An Examination of the Experiences and Perceptions of Multicultural Community Link Workers. Journal of Cross-Cultural Gerontology [Internet]. 2011 2011/12/01; 26(4):[365-77 pp.]. Available from: https://doi.org/10.1007/s10823-011-9155-9.
3. Australian Institute of Health and Welfare. Disability in Australia: trends in prevalence, education, employment and community living. Canberra, Australia. Bulletin no. 61. Cat. no. AUS 103. AIHW; 2008. Available from: https://www.aihw.gov.au/getmedia/c11c595b-1531-4ca9-95ab-071c1b68d8e9/bulletin61.pdf.aspx?inline=true.

4. Canuto K, Harfield S, Wittert G, Brown A. Listen, understand, collaborate: developing innovative strategies to improve health service utilisation by Aboriginal and Torres Strait Islander men. ANZJPH [Internet]. 2019; 43(4). Available from: https://onlinelibrary.wiley.com/pb-assets/assets/17536405/ANZJPH%202019-4_Full_Issue_for_Download-1565156916153.pdf#page=7.
5. Gilroy J, Donelly M, Colmar S, Parmenter T. Conceptual framework for policy and research development with Indigenous people with disabilities2013; (2):[42–58 pp.]. Available from: https://search.informit.org/doi/10.3316/informit.751842945817584.
6. Australian Health Ministers' Advisory Council. Aboriginal and Torres Strait Islander Health Performance Framework 2014 Report. Canberra, Australia: AHMAC; 2015. Available from: https://www.pmc.gov.au/sites/default/files/publications/Aboriginal_and_Torres_Strait_Islander_HPF_2014%20-%20edited%2016%20June2015.pdf.

7. Aboriginal Disability Network New South Wales. Telling it like it is: a report on community consultations with Aboriginal people with disability and their associates throughout NSW, 2004–2005. 2007. Available from: https://fpdn.org.au/telling-it-like-it-is/.

8. DiGiacomo M, Delaney P, Abbott P, Davidson PM, Delaney J, Vincent F. 'Doing the hard yards': carer and provider focus group perspectives of accessing Aboriginal childhood disability

services. BMC Health Services Research [Internet]. 2013 2013/08/19; 13(1):[326 p.]. Available from: https://doi.org/10.1186/1472-6963-13-326.
9. Ghosh S, Parish S. Prevalence and economic well-being of families raising multiple children with disabilities. Children and Youth Services Review [Internet]. 2013 2013/09/01/; 35(9):[1431-9 pp.]. Available from: https://www.sciencedirect.com/science/article/pii/S0190740913002132.
10. Lawton D. The number and characteristics of families with one or more than one disabled child1998. Available from: http://eprints.whiterose.ac.uk/75145/1/Document.pdf.
11. Kimura M, Yamazaki Y. The Lived Experience of Mothers of Multiple Children With Intellectual Disabilities. Qualitative Health Research [Internet]. 2013 2013/10/01; 23(10):[1307-19 pp.]. Available from: https://doi.org/10.1177/1049732313504828.
12. Ernst & Young Australia. NDIS Thin Markets Project Discussion paper to inform consultation,. 2019. Available from: https://engage.dss.gov.au/wp-content/uploads/2019/04/Thin-Markets-Project-Discussion-Paper-2019-04-05.pdf.

13. National Rural Health Alliance and National Disablity and Carer Alliance. Roundtable Report: Implementation of DisabilityCare Australia in rural and remote areas,. 2013. Available from: https://www.ruralhealth.org.au/document/roundtable-report-implementation-disabilitycare-australia-rural-and-remote-areas-national.

14. Australian Commission on Safety and Quality in Health Care. Health literacy: Taking action to improve safety and quality. Sydney; 2014. Available from: https://www.safetyandquality.gov.au/sites/default/files/migrated/Health-Literacy-Taking-action-to-improve-safety-and-quality.pdf.

Foot Orthoses for people with Autism Spectrum Disorder

The content of this document is OFFICIAL.

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

Research question: Do foot orthoses provide a benefit to ambulation for people with Autism Spectrum Disorder?

Date: 25/11/2021

Requestor: Nawaal s47F - personal p

Endorsed by: Melinda s47F - personal privacy

Cleared by: Melinda s47F - personal privacy

1. Contents

2. Summary

There is a lack of evidence for the effectiveness of foot orthoses for people with Autism Spectrum Disorder (ASD). However, there is some indication that foot orthoses can assist in treating and managing conditions associated with ASD. Foot orthoses may help reduce toe-walking. There is very little evidence that orthoses can assist with mobility in people diagnosed with Developmental Coordination Disorder (DCD), a condition associated with ASD. However, there is evidence that foot orthoses assist with the management of pain and associated function for a variety of other conditions such as flat feet, high arches, bunions, juvenile idiopathic arthritis, rheumatoid arthritis and knee pain. Quality of studies vary.

3. Motor difficulties for people with Autism Spectrum Disorder

ASD is a neurodevelopmental disorder characterised by difficulties in social interaction and social communication, including restrictive, repetitive, and inflexible patterns of behaviour [1,2].

DSM 5 notes that people with ASD can often also experience motor deficits such as clumsiness and problems with gait (1). Motor deficits are included as ‘additional features supporting diagnosis’, though there is a growing body of evidence supporting the idea that motor deficits are a core feature of ASD [1,3,4,5].

In a study of 11,814 participants, Bhat et al find 86.9% of children with ASD are at risk of motor impairments. Zampella et al report that up to 76% of children with ASD meet the diagnostic

criteria for DCD. DCD is a motor disorder characterised by motor skills substantially below what is expected at a person's age [5]. People with ASD are at greater risk of low muscle tone (hypotonia) and apraxia [3,6].

Of particular interest is the prevalence of motor deficits that can affect gait. An earlier study on the prevalence of motor deficits in children with ASD finds 19% present with toe-walking, 9% with a gross motor delay and 2% with reduced ankle mobility [Table1,3]. A later study finds 68% of children with ASD have some form of gait abnormality [Table2,6]. Children with ASD are at higher risk of toe-walking [3,6,7]. Estimates of the prevalence of toe walking in people ASD range from 9% [8] to 20% [3,9,10]. A 2015 review found considerable disagreement over the specifics of a pattern of gait in people with ASD, concluding that deviations in gait are a common symptom of ASD [11]. This heterogeneity is echoed by Dufek et al, who observe that the participants in their study displayed varied patterns of gait but generally showed an increase in gait abnormalities [12].

Table 1. The prevalence of motor deficits in ASD.

The prevalence of motor deficits in ASD

Motor[a] deficits	Age groups (years)	Hypotonia	Apraxia	Toe-walking	Reduced ankle mobility[b]	Gross motor delay
Presence	All	79 (51%)	53 (34%)	30 (19%)	4 (2%)	14 (9%)
	2–6	52 (63%)	34 (41%)	21 (25%)	2 (2%)	10 (12%)
	7–18	27 (38%)	19 (27%)	9 (13%)	2 (3%)	4 (6%)
Absence	All	75 (49%)	101 (66%)	124 (81%)	150 (98%)	140 (91%)
	2–6	31 (37%)	49 (59%)	62 (75%)	81 (98%)	73 (88%)
	7–8	44 (62%)	52 (73%)	62 (87%)	69 (97%)	67 (94%)

[a] Numbers represent the number of children (percent of all children in the specific age group or all age groups) with or without the motor deficit.
[b] All the four children with reduced ankle mobility had history of toe-walking.

Table 2. Gait abnomalities in children with Autism.

Gait abnormalities in children with autism and their typically developing matched peers (percent).

Gait abnormalities	Children with autism ($n = 38$)	Peers ($n = 38$)
Wide-based	33	0
Apraxic	33	0
Posturing	25	11
Clumsy	20	0
Any abnormality (excluding toe-walking)	58	11
Toe-walking (observed on video only)	33	3
Any toe-walking (in office or on video)	45	3
Any gait abnormality (including any toe-walking)	68	13

Motor deficits in children can impact social interaction and communication [5]. However, that motor deficits are present in individuals with ASD does not indicate that they necessarily experience the deficit as an impairment or that they require a specific kind of support. As shown in Table 1, prevalence of motor deficits tends to reduce with age. Although this is likely not the case for people diagnosed with DCD [29]. Dietz and Khunsree argue that evidence for the harm of toe-walking is lacking and that beyond social stigma toe-walking may ultimately be a benign condition [13]. On the contrary, Herrin and Geil argue that there are short and long term harms to toe-walking including:

- decreased walking velocity due to decreased stride length and cadence

- greater risks for falling
- greater effort than normal gait
- contracted Achilles tendon
- equinus position of the foot/ankle complex
- lumbar spine hyperlordosis
- deformities of bones and soft tissues in the feet
- abnormal adult gait [14].

Leyden, Frung and Frick note that some biomechanical and gait changes have been noted in people toe-walking for years, though they temper this with the observation that long term consequences of toe-walking are generally unknown [8]. Mediating this disagreement to some extent, we can point out that some toe-walkers exhibit this behaviour more and some less, i.e. many people who toe-walk also show standard gait at times. In one study, participants walking barefoot displayed toe-walking behaviour in 36% of steps [15]. I have not found research to link frequency of toe-walking behaviour with real functional impact (ie. research linking percentage of tow-walking footfalls with substantial mobility deficits).

While it is clear from the evidence that people with ASD experience problems with gait and motor skills at a higher rate than people without ASD, they do not receive treatment at a higher rate and continue to be under-diagnosed with motor impairments and DCD [3].

4. Effectiveness of foot orthoses

4.1 What are foot orthoses?

An orthosis or orthotic device is an “externally applied device used to compensate for impairments of the structure and function of the neuro-muscular and skeletal systems” [16]. Common lower limb orthoses include:

- Toe – designed to wedge in between toes
- Insoles – able to slip inside shoes, available custom made or prefabricated, can be heel, ¾ length or full length
- Sub Malleolar – covers the whole foot but stopping below the ankle
- Supra Malleolar – covers the whole foot and ankle
- Ankle-Foot – covers all or part of the foot, the ankle and stops just below the knee, can be articulated or solid, lined or padded and with or without a sole
- Knee – covers knee joint and stops above the ankle and below the hip, can be custom moulded or prefabricated

- Knee-Ankle-Foot – covers all or part of the foot, over the ankle and knee and stops just below the hip joint, can be articulated at ankle or knee, fully or partly custom moulded
- Hip – usually covering lower back and hip joint stopping before the knee, custom moulded or prefabricated
- Knee-Hip-Ankle-Foot – covers all or part of the foot, over the ankle, knee and hip but should not obstruct movement of the spine [17,18].

4.2 Effectiveness of treatment

Foot orthoses are a commonly prescribed treatment and management technique for a variety of lower body pain and functional/mobility issues. Orthoses, prescription footwear and physical therapy are often called ‘conservative’ treatments to contrast these with surgical interventions [19].

A 2008 Cochrane review of 11 randomised control trials found evidence that custom made insoles can reduce the pain associated with high arches (pes cavus), juvenile idiopathic arthritis, rheumatoid arthritis and bunions (hallux valgus). The review found mixed evidence that custom insoles reduce pain of plantar fasciitis [20].

Results were mixed for different conditions. Use of custom insoles for at least 3 months decreases pain associated with high arches, improves function and quality of life [20,21]. Children experiencing juvenile idiopathic arthritis can benefit from custom insoles or prefabricated neoprene insoles. Both interventions were more effective than supportive footwear at reducing pain and disability and improving function. After 3 months of use, pain reduction was seen for patients with rear-foot pain associated with rheumatoid arthritis, but no change after 3 years compared with placebo. Improvements to function between treatment and control were not statistically significant. Custom insoles did not reduce pain in the metatarsophalangeal joint associated with rheumatoid arthritis any more than supportive shoes or non-custom orthoses. Custom insoles can help reduce pain associated with bunions. Surgery may be more effective at reducing pain though no statistically significant difference in function was found between the two treatments [20].

A 2011 Cochrane review into use of foot orthoses to treat knee pain found some evidence for a reduction in pain in the short term (6 weeks) but also an increase in problems like blisters and rubbing. There was no statistically significant difference in pain for patients treated with orthoses and those treated with physiotherapy. The patients who had physiotherapy scored higher on functional outcomes. However, the standard of evidence of the reviewed studies was VERY LOW on the GRADE scale [22].

A 2010 Cochrane review into the use of non-surgical treatments for children with flat feet (pes planus) found some evidence that custom made orthoses could assist with the reduction in pain. However the quality of the evidence was compromised by small sample sizes, risk of

bias and difficulty comparing data of the included studies. The authors note there is a lack of high quality evidence on the topic [23]. A later study found some evidence that foot orthoses can improve knee alignment in people with flat feet [26]. The sample size of this randomly controlled trial was quite small at 15 participants.

Foot orthoses, either insoles, full foot or ankle-foot, are often used to treat toe-walking in people with good ankle range of motion and who are deemed capable of gait re-education [7]. Herrin et al found use of ankle-foot orthoses controls toe walking but the effects do not last after treatment. The insole does not work as well as the ankle-foot orthosis but is less restrictive and there is more uptake by children and their parents [14]. The quality of this randomly controlled trial suffers from lack of masking of any kind and stopping the study at 6 weeks instead of 6 months as originally stipulated [7,14]. The authors argue their preliminary evidence supports a 'sequential orthotic treatment', where less restrictive orthoses (insoles) are trialled first and the patient can progressively move to more restrictive orthoses (ankle-foot) as required [14].

4.2.1 Difficulties with determining effectiveness of foot orthoses

Even when high quality studies can be found on the benefits or harms associated with types of foot orthoses, it can still be difficult to draw conclusions about the effectiveness of foot orthoses in general. Orthoses designed for the same purpose come in different styles, use different design and manufacture methods and can be made from a variety and combination of materials including plastic, foam rubber, leather, cork, carbon fibre, and metal [17]. For example, results for one type of custom moulded carbon fibre insole may not generalise to other types of insole. Many studies do not specify the type of foot orthosis used [24]. Available research uses different measures of effectiveness, making findings difficult to aggregate. Much of the research focusses on pain reduction and only secondarily on functional outcomes and quality of life. Much of the research on the effectiveness of orthoses involves children. We know that children often outgrow their podiatric issues even without treatment. This means long term studies should contend with age and development as a confounding variable [25].

Also of note, much of the available research is designed to assess orthoses as a time-limited treatment option [14]. One study focussing on the long term effects of foot orthoses on walking kinematics limit the time-frame of the study to just 4 months [26]. I have not been able to find much research relevant to ongoing management of functional deficits (an exception is Hawke et al. [20]).

4.3 Foot orthoses for people with ASD

I have not found any literature specifically focussing on prescription of foot orthoses for people with ASD. Valagussa et al [2018] mention only 2 studies that look at treatment of toe-walking in people with ASD. I have only found 3 papers that mention foot orthoses as a treatment option for people with ASD and none of them look at this option in depth [3,10,19].

A summary of evidence-based treatments for ASD endorsed by the European Society of Child and Adolescent Psychiatry only briefly mentions motor deficits and notes only occupational therapy as a possible treatment [27]. Martikyan, Kaur, and Patel point out that consideration of the particularities of ASD which might complicate treatment of toe-walking are absent from the current literature [19]. For example, Leyden, Frung and Frick conclude:

> current [idiopathic toe-walking] treatment guidelines do not include specific recommendations for patients with comorbid conditions like ASD, and nonoperative treatments may be more challenging in patients with ASD if the patient has difficulty complying with instructions, sensitivity to tactile foot sensations/manipulation or is disturbed by the noise of cast saws. Medical treatment decisions should consider family preference, severity of the patient's condition, as well as any comorbid conditions [8].

As shown in 3. Motor difficulties for people with Autism Spectrum Disorder, people with ASD are at a much higher risk of DCD [5]. Podiatrists in Australia tend to think foot orthoses will be a viable treatment option for people with DCD. However, according to one analysis, podiatrists more familiar with DCD are less likely to prescribe orthoses [28]. There is very little evidence to suggest foot orthoses will have positive outcomes for people with DCD.

5. Reasonable and necessary

There is evidence that prescription of foot orthoses assists patients to reduce pain and disability and increase function for some conditions. There are several gaps in evidence and difficulties in generalising based on the current body of available evidence.

Considering the available evidence outlined in 4. Effectiveness of foot orthoses, it is unlikely that the treating clinician will be able to say with certainty that the prescription of custom moulded foot orthoses will improve the participant's functional outcomes. However, the clinician may have very good reason to suppose that the orthoses are likely to improve a participant's functional mobility.

When assessing requests for custom moulded foot orthoses for participants with ASD, assessors should:

- compare the reason for the request with the evidence of functional impairment and likely functional outcomes. Is it expected that the orthoses will increase comfort, reduce pain, improve walking tolerance, endurance, posture or gait, reduce falls risk, improve functional performance of daily activities such as increased independence and participation etc.?
- check if the participant has trialled or used custom orthoses in the past and what evidence has been collected demonstrating their efficacy and benefits
- confirm whether the orthoses are required:
  - to achieve short term treatment goals

  - as an early intervention support
  - to substantially improve the life stage outcomes of the participant
  - to manage ongoing functional performance of daily activities
- determine any characteristics of the individual that might complicate a prescription of foot orthoses. For example, does the participant have particular sensory needs? What is the likelihood that they will refuse or abandon the orthosis? Will insistence on this treatment lead to behaviours of concern?
- consider the research evidence which suggests that while children often improve gait and posture with age, people with ASD are also under-diagnosed with motor and gait issues including DCD
- request information regarding other options that have been completed, trialled or considered. For example:
  - prefabricated foot orthoses or supportive footwear
  - physical therapy
  - serial casting
  - surgery.

6. References

1. American Psychiatric Association. Diagnostic and statistical manual of mental disorders (DSM-5 (R)). 5th ed. Arlington, TX: American Psychiatric Association Publishing; 2013.
2. International Classification of Disease 11th Revision [Internet]. World Health Organisation. [cited 2021 Sep 27]. Available from: https://icd.who.int/browse11/l-m/en
3. Ming X, Brimacombe M, Wagner GC. Prevalence of motor impairment in autism spectrum disorders. Brain Dev. 2007;29(9):565–70.
4. Bhat AN. Is motor impairment in Autism Spectrum Disorder distinct from Developmental Coordination Disorder? A report from the SPARK study. Phys Ther. 2020;100(4):633–44.
5. Zampella CJ, Wang LAL, Haley M, Hutchinson AG, de Marchena A. Motor skill differences in autism spectrum disorder: A clinically focused review. Curr Psychiatry Rep. 2021;23(10):64.
6. Shetreat-Klein M, Shinnar S, Rapin I. Abnormalities of joint mobility and gait in children with autism spectrum disorders. Brain Dev. 2014;36(2):91–6.
7. Caserta AJ, Pacey V, Fahey M, Gray K, Engelbert RH, Williams CM. Interventions for idiopathic toe walking. Cochrane Database Syst Rev. 2019;10:CD012363.

8. Leyden J, Fung L, Frick S. Autism and toe-walking: are they related? Trends and treatment patterns between 2005 and 2016. J Child Orthop. 2019;13(4):340–5.
9. Barrow WJ, Jaworski M, Accardo PJ. Persistent toe walking in autism. J Child Neurol. 2011;26(5):619–21.
10. Valagussa G, Trentin L, Signori A, Grossi E. Toe walking assessment in autism spectrum disorder subjects: A systematic review: Toe walking assessment in ASD. Autism Res. 2018;11(10):1404–15.
11. Kindregan D, Gallagher L, Gormley J. Gait deviations in children with autism spectrum disorders: a review. Autism Res Treat. 2015;2015:741480.
12. Dufek JS, Eggleston JD, Harry JR, Hickman RA. A comparative evaluation of gait between children with autism and typically developing matched controls. Med Sci (Basel) [Internet]. 2017;5(1). Available from: http://dx.doi.org/10.3390/medsci5010001
13. Dietz F, Khunsree S. Idiopathic toe walking: to treat or not to treat, that is the question. Iowa Orthop J. 2012;32:184–8.
14. Herrin K, Geil M. A comparison of orthoses in the treatment of idiopathic toe walking: A randomized controlled trial. Prosthet Orthot Int. 2016;40(2):262–9.
15. Michalitsis J, Murphy AT, Rawicki B, Haines TP, Williams C. Full length foot orthoses have an immediate treatment effect and modify gait of children with idiopathic toe walking. Gait Posture. 2019;68:227–31.
16. ISO 8549-1:2020(en) Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses [Internet]. International Standards Organisation. [cited 2021 Sep 27]. Available from: https://www.iso.org/obp/ui/
17. Orthoses glossary [Internet]. Queensland Health. [cited 2021 Sep 27]. Available from: https://www.health.qld.gov.au/mass/prescribe/orthoses/glossary
18. Black JA, Matheson I. Orthoses. In: Frowen P, O'Donnell M, Gordon Burrow J, Lorimer DL., editor. Neale's disorders of the foot clinical companion. London, England: Churchill Livingstone; 2010. p. 435–51.
19. Martikyan S, Kaur K, Patel O. Autism and Toe-walking – a review of the current literature. Extremitas. 2018;5:26-30.
20. Hawke F, Burns J, Radford JA, du Toit V. Custom-made foot orthoses for the treatment of foot pain. Cochrane Database Syst Rev. 2008;(3):CD006801.
21. Burns, J., Landorf, K., Ryan, M., Crosbie, J. and Ouvrier, R. Interventions for the prevention and treatment of pes cavus. Cochrane Database of Systematic Reviews, 2007;4, CD006154.
22. Hossain M, Alexander P, Burls A, Jobanputra P. Foot orthoses for patellofemoral pain in adults. Cochrane Database Syst Rev. 2011;(1):CD008402.

23. Rome K, Ashford RL, Evans A. Non-surgical interventions for paediatric pes planus. Cochrane Database Syst Rev. 2010;(7):CD006311.

24. Dars S, Uden H, Banwell HA, Kumar S. The effectiveness of non-surgical intervention (Foot Orthoses) for paediatric flexible pes planus: A systematic review: Update. PLoS One. 2018;13(2):e0193060.

25. Meyr AJ, Sansosti LE. Flatfoot Deformity. In: Tower DE, editor. Evidence-based podiatry: A clinical guide to diagnosis and management. 1st ed. Cham, Switzerland: Springer Nature; 2020.

26. Jafarnezhadgero A, Madadi-Shad M, Alavi-Mehr SM, Granacher U. The long-term use of foot orthoses affects walking kinematics and kinetics of children with flexible flat feet: A randomized controlled trial. PLoS One. 2018;13(10):e0205187.

27. Fuentes J, Hervás A, Howlin P, (ESCAP ASD Working Party). ESCAP practice guidance for autism: a summary of evidence-based recommendations for diagnosis and treatment. Eur Child Adolesc Psychiatry. 2021;30(6):961–84.

28. Smith M, Banwell HA, Ward E, Williams CM. Determining the clinical knowledge and practice of Australian podiatrists on children with developmental coordination disorder: a cross-sectional survey. J Foot Ankle Res. 2019;12(1):42.

29. Harris SR, Mickelson ECR, Zwicker JG. Diagnosis and management of developmental coordination disorder. CMAJ. 2015;187(9):659–65

7. Version control

Version	Amended by	Brief Description of Change	Status	Date
1.0	AHR908	Research request relating to prescription of orthoses for treating people with Autism Spectrum Disorder.	Approved	24/11/2021

Manual therapy to address neuromusculoskeletal function

The content of this document is OFFICIAL.

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters, they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

Research questions:

Is manual therapy delivered by AHPRA recognised professionals effective in improving functional outcomes for people presenting with neuromusculoskeletal symptoms?

Date: 08/08/2023

Requestor: Karyn s47F - personal privac

Endorsed by: n/a

Researcher: Aaron s47F - personal privacy

Cleared by: Stephanie s47F - personal privacy

1. Contents

2. Summary

This paper addresses the efficacy of manual therapy delivered by physiotherapists, chiropractors and osteopaths on functional outcomes for people experiencing neuromusculoskeletal symptoms.

Manual therapy comprises a variety of hands-on techniques primarily aimed to reduce pain and discomfort or improve range of motion in people with musculoskeletal disorders. It can be delivered by a variety of medical and allied health professionals or associated providers (Manual Therapy). Manual therapy may also address functional difficulties including impairment, activity limitation or participation restrictions for people experiencing neuromusculoskeletal symptoms (Functional outcome). Neuromusculoskeletal symptoms are associated with diseases, conditions or disorders of the neuromuscular system or the musculoskeletal system and can include discomfort, pain, paralysis or other loss of function (Neuromusculoskeletal symptoms).

There is evidence suggesting manual therapy can be effective at managing pain and discomfort and improving physical functioning for people with musculoskeletal-related pain conditions, especially low back pain and neck pain. Minimal evidence exists related to improvements in function for people with non-pain related conditions. While some evidence points to improvements in quality of life, most functional outcomes relate to improving range of motion or mobility. No evidence was found that manual therapy leads to a reduction in other activity limitations or participation restrictions.

Due the wide scope of practice of manual therapy, research papers pooling results can make it difficult to identify individual trends. Many therapeutic techniques utilise mixed modalities, so it is difficult to determine whether one or all of the modalities taken together are producing an effect. In addition, the current literature is largely of low or very low quality with significant risk of bias. Refer to 4. Efficacy of manual therapy for further details.

Despite the number of existing studies, the quality of the literature has prevented many clinical practice guidelines from offering strong endorsement of manual therapy techniques. Clinical practice guidelines generally offer conditional acceptance of manual therapy. Stronger evidence exists for the benefits of short-term manual therapy, with less evidence that it is efficacious as a long-term management strategy. Further, evidence suggests manual therapy is most optimally delivered alongside active exercise treatment. However, there is also some suggestion that manual therapy, as a form of passive exercise, may be offered as an alternative to patients who are unable to engage in an active exercise program. Refer to 5. Clinical practice guidelines for further details.

Other TAB research

For further examination of the evidence-base for chiropractic, refer to RES 264 Efficacy of chiropractic treatment. RES 316 Melillo Method describes chiropractic-related method aimed to address neurodevelopmental conditions.

RES 276 Sensory based therapy contains discussion of some evidence that massage may target behaviours of concern. RES 191 Massage Therapy as a Treatment for Multiple Sclerosis provides a literature review of massage therapy for use in that cohort.

General information on physiotherapy interventions for various conditions can be found in RES 203 Therapy Best Practice.

Acupuncture is sometimes referred to as a manual therapy. For a consideration of acupuncture refer to:

- RES 190 Acupuncture as a treatment for Mitochondrial Encephalopathy Lactic Acidosis Stroke-like Episodes
- RES 175 Treatment of Chronic Migraine
- RES 211 Therapy Programs for Lupus.

3. Scope and terminology

The efficacy of manual therapy delivered by physiotherapists, chiropractors and osteopaths on functional outcomes for people experiencing neuromusculoskeletal symptoms is explored through discussion of clinical practice guidelines and systematic reviews of manual therapy interventions.

Neuromusculoskeletal symptoms

Neuromusculoskeletal symptoms are associated with diseases, conditions or disorders of the neuromuscular system or the musculoskeletal system and can include discomfort, pain, paralysis or other loss of function.

Conditions leading to neuromusculoskeletal symptoms can include:

- pain conditions such as chronic back or neck pain, arthritis, fibromyalgia or headache disorders
- significant injury such as spinal cord injury, stroke or traumatic brain injury
- neurological conditions such as Parkinson's disease, cerebral palsy, or multiple sclerosis (World Health Organisation, 2023a; Wang et al, 2022; Briggs et al, 2018).

Manual therapy

Manual therapy refers to a variety of hands-on physical therapy techniques. The aim is usually to reduce pain, swelling and inflammation, induce relaxation or improve joint range of motion and muscle flexibility. Manual therapy can involve soft tissue techniques, manipulation or mobilisation (NICE, 2021; Young and Argaez, 2020), though the distinctions between these practices may break down in some cases (NICE, 2021b).

Soft tissue techniques target muscles, tendons, or ligaments. This can include massage, muscle energy technique, strain/counterstrain and myofascial/trigger point release (NICE, 2021; Locher & Beyer, 2021; Franke et al, 2015).

Manipulation and mobilisation target joints. Manipulation is the application of force to affect short, quick movements near the end of or beyond the normal range of a joint (LaPelusa & Bordoni, 2023; NICE, 2021). In contrast, mobilisation is often defined as application of force leading to longer, slower movements of target joints (NICE, 2021; Gross et al, 2015). Mobilisation is also sometimes used to refer to the movement of joints regardless of amplitude or velocity (Krøll et al, 2021).

These are often thought of as passive techniques because the therapist or practitioner moves the tissue, joint or limb while client is relaxed. They are distinguished from active techniques such as exercise programs (Ganderton & King, 2020; Canadian Agency for Drugs and Technologies in Health (CADTH), 2016). However, this distinction is challenged by some researchers and clinicians who point out that some manual therapy techniques require the client's active participation, such as pushing back or tensing in response to the practitioner's movements (Physio Network, 2021).

Manual therapy techniques are commonly used by physiotherapists, chiropractors, osteopaths and massage therapists (NICE, 2021; Franke et al, 2015; Gross et al, 2015) but may also be used by:

- other allied health professionals such as occupational therapists or exercise physiologists
- medical professionals such as general practitioners, physiatrists, osteopathic doctors (in the USA)
- traditional or alternative medicine practitioners uses practices such as myotherapy, Chinese medicine, acupuncture/acupressure, or the Melillo Method
- others such as personal trainers and coaches (Locher & Beyer, 2021; Canadian Agency for Drugs and Technologies in Health, 2016).

This paper will focus on manual therapy as it is employed by allied health professionals regulated by AHPRA including physiotherapists, chiropractors, and osteopaths.

Functional outcome

A functional outcome generally contrasts with a clinical outcome. This distinction aims to highlight the differences between an intervention having some observable effect on bodily systems and an intervention improving a person's functioning. However, the distinction is not often clearly drawn and may be used differently in different contexts. For example, reduction in pain is a common clinical outcome though it may have significant functional implications. Pain may even count as an impairment in cases of chronic or neuropathic pain (Health Direct, 2022; Young and Argaez, 2020; Franke et al, 2015; Gross et al, 2015).

The World Health Organisation's (WHO) International Classification of Functioning, Disability and Health (ICF) distinguishes three levels of functioning: of bodily systems and structures; of the whole person; of the whole person in their social context. Interruptions to functioning can occur at either level and are referred to as impairments, activity limitations and participation restrictions respectively (WHO, 2023b).

The *National Disability Insurance Scheme Act 2013* and the *National Disability Insurance Scheme (Supports for Participants) Rules 2016* signals the NDIA's focus on activity limitations and participation restrictions (e.g. NDIS Act, s24; NDIS Rules, s5.8). Where possible, this paper will focus on whether an intervention is able to achieve functional outcomes as measured by a reduction in activity limitations or participation restrictions in domains including communication, social interaction, learning, mobility, self-care, self-management (NDIS Act, s24.1(c)). However, where this information is not available, this paper will examine pain or functional outcomes in reducing impairment of bodily systems or structures.

4. Efficacy of manual therapy

Most evidence regarding the efficacy of manual therapies relates to the treatment of pain conditions. Generally, where evidence of improvement in function exists, it is also for pain conditions. However, according to a recent systematic review, the evidence is equivocal:

> In most cases, treatment with manual therapy did not result in statistically significant differences when compared to sham therapy or no treatment in adults with persistent or chronic non-cancer back and neck pain; however, there was some evidence that suggested treatment with manual therapies improved pain, functional status, and health-related quality of life (Young and Argaez et al, 2020, p.4).

An evidence review informing the NICE guideline for osteoarthritis (2022a) notes:

> while there were some benefits due to manual therapy this was often in outcomes that were imprecise or heterogenous with inconsistency that could not be resolved by subgroup analysis. … [There] was insufficient evidence to indicate a benefit from manual therapy alone. However, there was evidence of benefit for manual therapy when combined with exercise.

Evidence suggests manual therapy is most effective if performed as an adjunct to active exercise treatment (Runge et al, 2022; Ganderton & King, 2020).

4.1 Pain

Comparing mixed modality manual therapy with standard treatment, an evidence review informing the NICE guideline for chronic pain found low quality evidence showing no reduction in pain up to 3 months, but some reduction in pain after 3 months (NICE, 2021a). This contrasts with other reviews which find little evidence of benefit in the long term (Runge et al, 2022; Ganderton & King, 2020).

Franke et al (2015) found low quality evidence suggesting muscle energy techniques are not effective in the treatment of low back pain. Chen et al (2020) did not find evidence that myofascial release therapy reduces pain for people with lower back pain. There is some evidence that massage is an effective pain relief for people with multiple sclerosis. However, the evidence is of consistently low or critically low quality with serious risk of bias (NICE, 2022c).

Rubenstein et al (2012) found low quality evidence that spinal manipulation treatment is no more effective than sham control, and no more effective than any other therapy in the treatment of lower back pain. Gross et al (2015) found conditional support for the use of manipulation and mobilisation in the treatment of neck pain. NICE's review of chronic pain management (2021a) found low quality evidence of reduction in pain for soft tissue techniques compared with usual care and manipulation / mobilisation compared with usual care up to 3 months. A recent narrative review (Licciardone et al, 2021) argues there is sufficient evidence for the effectiveness of osteopathic manipulative treatment (OMT) for lower back pain, citing large effect sizes comparable to some pain medications. However, the authors do not report the quality of these studies. They also note insufficient evidence for the effectiveness of OMT for any other condition. A recent review of systematic reviews of OMT found evidence of possible reduction in lower back and neck pain (Bagagiolo et al, 2022). However, all systematic reviews included in Bagagiolo et al were rated as low or critically low quality.

4.2 Functional outcomes

Some evidence exists that manual therapy can improve the physical functioning of people experiencing acute or chronic pain conditions. Low or very low quality evidence shows mixed modality manual therapy can improve physical functioning (as measured by either 5 minute walk, sit to stand, Roland Morris Disability Questionnaire, Oswestry Disability Index, Canadian Occupational Performance Measure) compared to usual care for people with chronic pain (NICE, 2021a). Multiple sessions utilising manipulation of the cervical spine may lead to improvement in function and quality of life for people with neck pain and may be more effective than some analgesics (Gross et al, 2015). Bagagiolo et al (2022) report promising evidence that OMT improves functional status in patients with lower back pain and neck pain. However, there was notable heterogeneity due to use of different outcome measures. preventing making firm conclusions.

Runge et al (2022) determined there is evidence for improvement on some measures of physical function after manual therapy for people with hip and knee arthritis, but not for performance-based measures of function.

Very little research was found to show improvements in function after manual therapy for conditions not associated with pain. Some studies show improvements in mobility and range of motion for people with Parkinson's disease after OMT, though the studies generally have small sample sizes and show inconsistent effects (Li et al, 2021).

5. Clinical practice guidelines

No guidelines were found that recommended manual therapy should not be offered in any circumstance. Some guidelines withhold a recommendation for or against due to lack of evidence (NICE, 2022c; 2021b; 2019a; CADTH, 2016). Most guidelines offer conditional recommendations for manual therapy, with some indicating circumstances in which manual therapy should not be offered (Lin et al, 2020; Hawk et al, 2020; Oliveira et al, 2018; CADTH, 2016). Recommendations concerning manual therapy can vary depending on:

- technique (spinal manipulation, massage, traction etc.)
- condition (chronic pain, Parkinson's disease, cerebral palsy etc.)
- target outcome (pain, spasticity, mobility etc.)
- chronicity (e.g., acute or chronic pain)
- intended duration (short- or long-term pain management)
- effectiveness of other treatments
- simultaneous treatments (with or without active exercise) (Lin et al, 2020; Hawk et al, 2020; Oliveira et al, 2018; CADTH, 2016).

Some clinical guidelines recommend against manual therapy in the treatment of pain in some circumstances. NICE (2020) recommend against offering traction for people with lower back pain or sciatica. Other guidelines may recommend manual therapy for acute pain but not chronic pain (Oliveira et al, 2018) or against its long-term use (CADTH, 2016).

5.1 Simultaneous active exercise

Many guidelines recommend offering manual therapy with simultaneous active exercise intervention for the management of pain. Lin et al (2020) note a consensus strongly in favour of simultaneous active exercise to treat musculoskeletal pain. This is also the NICE approach to manual therapy for lower back pain (2020) and for osteoarthritis (2022a) but not for chronic pain in general (2021b). Their guideline for people with spondyloarthritis over 16 years recommends an exercise program delivered by a specialist physiotherapist. The guideline does not clarify whether the exercises should include active, passive or a combination of modalities (NICE, 2017c). The American Academy of Orthopaedic Surgeons (AAOS) offers a limited recommendation in favour of manual therapy with simultaneous exercise for knee arthritis (AAOS, 2021).

Hawk et al (2020) report on a Delphi consensus statement of 58 Doctors of Chiropractic regarding best practice treatment for musculoskeletal pain. They recommend clinicians emphasise the importance of active exercise alongside passive manual therapy for their clients. However, Hawk et al assume manual therapy will be prescribed and suggest active exercise is also prescribed where possible. This contrasts with the consensus described in Lin et al (2020), who suggest manual therapy should only be prescribed if active exercise is also prescribed.

Recommendations in favour of simultaneous active exercise treatment should be considered in the context of clear consensus on the benefits of active exercise and maintaining physical activity for most populations (NICE, 2022a; 2022b; 2022c; 2021; 2020; 2019b; 2017a; 2017b; 2017c; 2016). For example, the NICE guideline for osteoarthritis provides a rationale for this recommendation:

> The committee acknowledged recent evidence that showed some clinical benefits of manual therapy for hip and knee osteoarthritis, with no evidence being identified for other joint sites. However, the benefits were stronger if manual therapy was combined with exercise. Clinical and economic evidence showed that exercise alone was more effective than both manual therapy alone and the combination of manual therapy and exercise. So, the committee concluded that manual therapy should only be considered alongside therapeutic exercise (NICE, 2022a, p.42).

5.2 Functional outcomes

Few guidelines offer recommendations for outcomes other than pain management. NICE guidelines for treatment of spasticity (2016) and management of cerebral palsy (2017b; 2019a) do not make recommendations around manual therapy due to lack of evidence. The NICE

guideline for Parkinson's disease (2017a) suggests clinicians can consider the Alexander technique to address balance and motor function problems.

The NICE guideline for people with motor neurone disease (2019b) suggests clinicians can consider a tailored exercise program to address range of movement, contractures, stiffness and discomfort, function and quality of life. The programme can include passive exercises depending on the client's needs and abilities. The guideline does not refer to any evidence that passive exercise programmes can address any of the outcomes cited.

For people recovering after a traumatic injury, NICE (2022b) suggests that clinicians:

- offer a gait training program that includes passive stretches
- consider both passive and active exercises to maintain or improve range of movement
- offer massage for management of scar tissue.

Passive stretching after traumatic injury is described in the context of controlled motion devices or continuous passive motion machines. It is not clear whether the recommendations cover manual therapy without such devices.

6. References

American Academy of Orthopaedic Surgeons. (2021). Management of Osteoarthritis of the Knee (Non-Arthroplasty) Evidence-Based Clinical Practice Guideline (3rd Edition). https://www.aaos.org/oak3cpg

Bagagiolo, D., Rosa, D., & Borrelli, F. (2022). Efficacy and safety of osteopathic manipulative treatment: an overview of systematic reviews. *BMJ open*, *12*(4), e053468. https://doi.org/10.1136/bmjopen-2021-053468

Briggs, A. M., Woolf, A. D., Dreinhöfer, K., Homb, N., Hoy, D. G., Kopansky-Giles, D., Åkesson, K., & March, L. (2018). Reducing the global burden of musculoskeletal conditions. *Bulletin of the World Health Organization*, *96*(5), 366–368. https://doi.org/10.2471/BLT.17.204891

Canadian Agency for Drugs and Technologies in Health. (2016). *Physical Therapy Treatments for Chronic Non-Cancer Pain: A Review of Guidelines*. https://www.ncbi.nlm.nih.gov/books/NBK409574

Franke, H., Fryer, G., Ostelo, R. W., & Kamper, S. J. (2015). Muscle energy technique for non-specific low-back pain. *The Cochrane database of systematic reviews*, (2), CD009852. https://doi.org/10.1002/14651858.CD009852.pub2

Ganderton, C. & King, M. (2020, November). Physio, chiro, osteo and myo: what's the difference and which one should I get? *The Conversation*.

https://theconversation.com/physio-chiro-osteo-and-myo-whats-the-difference-and-which-one-should-i-get-149993

Gross, A., Langevin, P., Burnie, S. J., Bédard-Brochu, M. S., Empey, B., Dugas, E., Faber-Dobrescu, M., Andres, C., Graham, N., Goldsmith, C. H., Brønfort, G., Hoving, J. L., & LeBlanc, F. (2015). Manipulation and mobilisation for neck pain contrasted against an inactive control or another active treatment. *The Cochrane database of systematic reviews*, (9), CD004249. https://doi.org/10.1002/14651858.CD004249.pub4

Hawk, C., Whalen, W., Farabaugh, R. J., Daniels, C. J., Minkalis, A. L., Taylor, D. N., Anderson, D., Anderson, K., Crivelli, L. S., Cark, M., Barlow, E., Paris, D., Sarnat, R., & Weeks, J. (2020). Best Practices for Chiropractic Management of Patients with Chronic Musculoskeletal Pain: A Clinical Practice Guideline. *Journal of alternative and complementary medicine*, *26*(10), 884–901. https://doi.org/10.1089/acm.2020.0181

HealthDirect. (2022). *Nerve pain (neuralgia)*. https://www.healthdirect.gov.au/nerve-pain

Krøll, L. S., Callesen, H. E., Carlsen, L. N., Birkefoss, K., Beier, D., Christensen, H. W., Jensen, M., Tómasdóttir, H., Würtzen, H., Høst, C. V., & Hansen, J. M. (2021). Manual joint mobilisation techniques, supervised physical activity, psychological treatment, acupuncture and patient education for patients with tension-type headache. A systematic review and meta-analysis. *The journal of headache and pain*, *22*(1), 96. https://doi.org/10.1186/s10194-021-01298-4

LaPelusa, A., & Bordoni, B. (2023). High-Velocity Low-Amplitude Manipulation Techniques. In StatPearls. *StatPearls Publishing*. https://www.ncbi.nlm.nih.gov/books/NBK574527/

Licciardone, J. C., Schultz, M. J., & Amen, B. (2020). Osteopathic Manipulation in the Management of Chronic Pain: Current Perspectives. *Journal of pain research*, 13, 1839–1847. https://doi.org/10.2147/JPR.S183170

Lin, I., Wiles, L., Waller, R., Goucke, R., Nagree, Y., Gibberd, M., Straker, L., Maher, C. G., & O'Sullivan, P. P. B. (2020). What does best practice care for musculoskeletal pain look like? Eleven consistent recommendations from high-quality clinical practice guidelines: systematic review. *British journal of sports medicine*, *54*(2), 79–86. https://doi.org/10.1136/bjsports-2018-099878

Locher, H. & Beyer, L. (2021).Manual medicine, manual therapy. *Manuelle Medizin* 59, 254–266. https://doi.org/10.1007/s00337-021-00817-3

National Disability Insurance Scheme (Supports for Participants) Rules 2016 (Cth). https://www.legislation.gov.au/Details/F2018C00165

National Disability Insurance Scheme Act 2013 (Cth). https://www.legislation.gov.au/Details/C2022C00206

National Institute of Health Care Excellence. (2022a). *Osteoarthritis in over 16s: diagnosis and management (NG226)*. www.nice.org.uk/guidance/ng226

National Institute of Health Care Excellence. (2022b). *Rehabilitation after traumatic injury (NG211)*. www.nice.org.uk/guidance/ng211

National Institute of Health Care Excellence. (2022c). *Multiple sclerosis in adults: management (NG220)*. www.nice.org.uk/guidance/ng220

National Institute of Health Care Excellence. (2021a). *Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain (NG193) - Evidence review for manual therapy for chronic primary pain*. https://www.nice.org.uk/guidance/ng193/evidence/i-manual-therapy-for-chronic-primary-pain-pdf-326591532180

National Institute of Health Care Excellence. (2021b). *Chronic pain (primary and secondary) in over 16s: assessment and management (NG193)*. www.nice.org.uk/guidance/ng193

National Institute of Health Care Excellence. (2020). *Low back pain and sciatica in over 16s: assessment and management (NG59)*. www.nice.org.uk/guidance/ng59

National Institute of Health Care Excellence. (2019a). *Cerebral palsy in adults (NG119)*. www.nice.org.uk/guidance/ng119

National Institute of Health Care Excellence. (2019b). *Motor neurone disease: assessment and management (NG42)*. www.nice.org.uk/guidance/ng42

National Institute of Health Care Excellence. (2017a). *Parkinson's disease in adults (NG71)*. www.nice.org.uk/guidance/ng71

National Institute of Health Care Excellence. (2017b). *Cerebral palsy in under 25s: assessment and management (NG62)*. www.nice.org.uk/guidance/ng62

National Institute of Health Care Excellence. (2017c). *Spondyloarthritis in over 16s: diagnosis and management (NG65)*. www.nice.org.uk/guidance/ng65

National Institute of Health Care Excellence. (2016). *Spasticity in under 19s: management (CG145)*. www.nice.org.uk/guidance/ng145

Oliveira, C. B., Maher, C. G., Pinto, R. Z., Traeger, A. C., Lin, C. C., Chenot, J. F., van Tulder, M., & Koes, B. W. (2018). Clinical practice guidelines for the management of non-specific low back pain in primary care: an updated overview. *European spine journal: official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society*, *27*(11), 2791–2803. https://doi.org/10.1007/s00586-018-5673-2

Physio Network. (2021). *Manual Therapy: Always a Passive Treatment?* https://www.physio-network.com/blog/manual-therapy-passive/

Runge, N., Aina, A., & May, S. (2022). The Benefits of Adding Manual Therapy to Exercise Therapy for Improving Pain and Function in Patients With Knee or Hip Osteoarthritis: A Systematic Review With Meta-analysis. *The Journal of orthopaedic and sports physical therapy*, *52*(10), 675–A13. https://doi.org/10.2519/jospt.2022.11062

Wang, Y., Hu, M., Li, L., Xu, D., Liu, H., Wang, X., & Li, K. (2022). Editorial: Physical exercise for age-related neuromusculoskeletal disorders. *Frontiers in aging neuroscience*, 14, 1099417. https://doi.org/10.3389/fnagi.2022.1099417

World Health Organization. (2023a). *Neuromusculoskeletal and movement-related functions*. International Classification of Functioning, Disability and Health, 11th revision. https://icd.who.int/dev11/l- icf/en#/http%3a%2f%2fid.who.int%2ficd%2fentity%2f161488596

World Health Organization. (2023b). *International Classification of Functioning, Disability & Health*. International Classification of Diseases for Mortality and Morbidity Statistics, 11th revision, Reference Guide. https://icdcdn.who.int/icd11referenceguide/en/html/index.html#international-classification-of-functioning-disability-health-icf

Young, C., & Argáez, C. (2020). *Manual therapy for chronic, non-cancer back and neck pain: a review of clinical effectiveness*. Canadian Agency for Drugs and Technologies in Health. https://www.ncbi.nlm.nih.gov/books/NBK562937/pdf/Bookshelf_NBK562937.pdf

Physiotherapy and exercise for progressive neurological conditions

The content of this document is OFFICIAL.

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters, they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters

Research questions:

What is considered best practice for the frequency and duration of physiotherapy and exercise physiology for progressive neurological conditions?

Are there any contraindications for use of a delegated care model for these supports with this population (e.g. using therapy assistants)?

What are the risks and contraindications of physiotherapy and exercise physiology based on disease progression with these populations (i.e. is there a time when hands on therapy should not be provided as risks outweigh benefits)?

Date: 29/4/2024

Requestor: Sarah s47F - personal priv

Endorsed by: Shannon s47F - personal pri

Researcher: Aaron s47F - personal privacy

Cleared by: Aaron s47F - personal privacy

1. Contents

2. Summary

This paper considers the use of physiotherapy and exercise interventions for people with progressive neurological conditions including amyotrophic lateral sclerosis (ALS) and motor neuron disease (MND), Parkinson's disease (PD), multiple sclerosis (MS), and muscular dystrophy (MD). This paper focusses on evidence of optimal frequency and duration of physiotherapy and exercise interventions, risks associated with interventions, differing care for early or late stages of progression and the use of therapy assistants through a delegated care model.

No studies were found that address the role of therapy assistants in the delivery of physiotherapy or exercise interventions for people with progressive neurological conditions. Some evidence suggests that the use of therapy assistants in acute hospital settings and general community settings is safe and effective. This evidence is uncertain and further research is required.

There is limited evidence regarding optimal dosage of physiotherapy and exercise interventions for people with progressive neurological conditions. Clinical practice guidelines for PD and MS provided recommendations for frequency and duration of physiotherapy and exercise interventions. However, it is likely that these recommendations are based primarily on clinical judgement rather than published evidence. One 2023 systematic review was able to determine that at least twice weekly sessions of more than 40 minutes is an effective dose of exercise intervention for the improvement of balance in MS (Corrini et al, 2023). No other studies could provide evidence-based dosage recommendations.

Where evidence is not clear, guidelines generally recommend that type, frequency, duration and intensity of physiotherapy or exercise interventions should be determined individually based on the needs and preferences of the person receiving treatment.

Despite some issues with the proper reporting of adverse events in experimental studies, exercise interventions for people with progressive neurological conditions are generally believed to be safe, provided that standard safety precautions are observed.

There is little evidence regarding safety and effectiveness of physiotherapy and exercise interventions for people at late stages of progressive neurological conditions. Most research focusses on people with mild to moderate symptom severity.

3. Previous TAPIB research

Other relevant TAPIB research papers include:

- RES 322 Manual therapy to address neuromusculoskeletal function
- RES 321 Osteopathy
- RES 318 Exercise physiology and stroke
- RES 289 Lokomat Therapy

- RES 264 Chiropractic
- RES 233 Virtual reality as a support tool
- RES 191 Massage Therapy as a Treatment for Multiple Sclerosis

4. Therapy assistants

Therapy assistants are

> support staff who complete clinical and non-clinical tasks under the supervision and delegation of an allied health professional. Clinical tasks include any direct therapeutic interventions provided to patients such as exercise therapy and education, while non-clinical tasks may include administration duties (eg, completing paperwork for equipment hire), maintenance of equipment and cleaning the clinical environment. Because allied health assistants cannot perform clinical tasks that involve diagnosing or assessing patient health conditions, allied health professionals must perform a comprehensive assessment of the patient and prescribe appropriate therapy prior to delegating the allied health assistant to perform any clinical tasks. (Snowdon et al, 2024, p.2).

In a survey of 232 UK-based physiotherapists, 81% of respondents indicated that they at least sometimes delegate the supervision of prescribed exercises to therapy assistants (Sarigiovannis et al, 2022). The authors also found that delegation of clinical tasks to therapy assistants was more likely in less complex cases where there is a straightforward treatment plan. There is a perception that increased reliance on therapy assistants may compromise the quality or safety of the intervention (Snowdon et al, 2024). However, existing evidence suggests that physiotherapy or exercise interventions delivered by a therapy assistant are likely safe (Lau et al, 2024; Snowdon et al, 2020).

No studies were found that address the role of therapy assistants in the delivery of physiotherapy or exercise interventions for people with progressive neurological conditions. Where there is minimal research to date, there is a growing interest in the role of therapy assistants in completing clinical physiotherapy tasks (Snowdon et al, 2024; Sarigiovannis et al, 2023). Current research mostly considers the addition of therapy assistants to usual care rather than a model where physiotherapy or exercise interventions are primarily delivered by a therapy assistant (Snowdon et al, 2024; Lau et al, 2024; Snowdon et al, 2020). Some evidence points to the efficacy and safety of physiotherapy or exercise interventions delivered by therapy assistants. Additional supervised exercise sessions may improve outcomes regardless of whether it is delivered by a physiotherapist or therapy assistant (Snowdon et al, 2024; Lau et al, 2024; Baumann et al, 2023a-b; Sarigiovannis et al, 2023; Sarigiovannis et al, 2022; Sarigiovannis et al, 2021). Much of the research is based in a hospital setting and the roles of physiotherapist and therapy assistant are frequently poorly reported, so results may not generalise across all models of therapy assistance or patient cohorts (Sarigiovannis et al, 2021; Snowdon et al, 2020).

5. Amyotrophic lateral sclerosis / motor neuron disease

5.1 Frequency and duration

We did not find any reviews able to determine optimal frequency or duration of exercise or physiotherapy interventions for people with ALS/MND. One review (Zhou et al, 2022) showed inconsistent evidence that more intensive exercise training could slow the decline in functional capacity. However, the authors do not specify what they mean by ‘intensive’.

A 2023 meta-analysis including 17 studies was unable to determine optimal exercise dosage due to the variability of intervention: “frequency ranged from 2×/week to 3×/day, up to 7 days/week, with repetitions of sets ranging from 20 to 25, intensity ranging from 30 to 60% of a patient’s maximum value, and treatment duration ranging from 2 weeks to 2 years” (Donohue et al, 2023, p.19). Meng et al (2020) and Papadopolou et al (2024) were similarly unable to determine the most effective frequency, intensity, type, timing or duration of exercise-based interventions.

5.2 Risks

Researchers report some reluctance to prescribe exercise for people with ALS/MND due to possibility that exercise might lead to fatigue and faster progression of symptoms (MND Australia, 2021). However, recent reviews have found no serious adverse events in studies of exercise or physiotherapy intervention for people with ALS/MND (Papadopolou et al, 2024; Donohue et al, 2023; Meng et al, 2020). Researchers suggest that physiotherapy or exercise-based interventions are likely safe for people with ALS/MND.

5.3 Stage of progression

Minimal evidence is available for the efficacy of physiotherapy or exercise programs for people with more advanced ALS/MND. Donahue et al (2023) find some low certainty evidence that exercise programs are beneficial in early stages of disease progression. However, all of the studies included in their review explore exercise intervention only on those with low to moderate symptom severity.

Ireland’s *Guidelines for the physiotherapy management of Motor Neuron Disease* (O’Callaghan, 2014), suggests physiotherapy treatment plans differentiate early, middle and late stages of progression. During the late stage, strategies to maintain function and manage symptoms may include:

- a stretching program
- active and passive range of movement exercises
- the use of assistive technology such as motomed or tilt table.

While evidence is presented for the efficacy of exercise at the early stages of MND, recommendations for strategies at the middle and late stages are based on clinical judgment of the authors.

6. Parkinson's Disease

6.1 Frequency and duration

There is no consensus on optimal frequency or duration of physiotherapy or exercise interventions for people with Parkinson's disease. Reviews report average frequency and duration of interventions used in studies but are unable to determine best practice timing (Ernst et al, 2024; El Hayek et al, 2023; Osborne et al, 2022; Grimes et al, 2019; NICE, 2017; Keus et al, 2014).

El Hayek et al (2023) reviewed 46 studies to determine most effective types, timing, frequency, duration, and outcomes of physiotherapy and exercise for people with Parkinson's disease. They found no significant difference between interventions and comparisons for frequency, duration or number of sessions.

A 2024 Cochrane review of studies on exercise intervention for people with Parkinson's disease was unable to draw conclusions regarding the optimal frequency of exercise intervention (Ernst et al ,2024). The authors observed a beneficial effect on functional mobility and balance in studies lasting longer than 12 weeks. However, they did not observe a significant effect of intervention duration on other outcomes.

Of four clinical practice guidelines that recommend the use of physiotherapy, exercise or physical activity for people with Parkinson's disease, only one provides recommendations regarding frequency and duration of activity (Osborne et al, 2022; Grimes et al, 2019; NICE, 2017; Keus et al, 2014). The *European Physiotherapy Guideline for Parkinson's Disease* (Keus et al, 2014) includes recommendations for minimum treatment period for seven physiotherapy modalities (refer to Table 1). However, the Guideline Development Group (GDG) responsible for the recommendations also note:

> Evidence-based information on the optimal number of sessions a week, session time and length of a treatment period are unavailable. These decisions will depend on the treatment goal, the selected intervention, the potential of the [person with Parkinson's disease] and the response to the treatment. GDG recommendations for minimum treatment period, frequency and session duration for each intervention category provided in this chapter are based on the averages of controlled clinical trials (CCTs) supportive to the 'for' recommendations (Keus et al, 2014, p.64)

Further, the GDG suggests that the optimal treatment period, duration and intensity will most likely never be determined due to the varied fitness levels, functional capacity and preferences of people with Parkinson's disease (Keus et al, 2014, p.72). This judgement is implicitly supported by the most recent clinical guideline from the American Physical Therapy

Association (Osborne et al, 2022). Osborne et al review 11 physiotherapy interventions and concludes there is still insufficient evidence to determine optimal dosing for any of the reviewed interventions.

Table 1 Minimum recommended treatment period for physiotherapy interventions (source: Keus et al, 2014)

Note: This table contains recommended minimum treatment periods from the *European Physiotherapy Guideline for Parkinson's Disease*. These recommendations are not the optimal dosage, but rather the average treatment period of studies that found beneficial effects of the intervention.

Intervention	Minutes	Per week	Weeks
Conventional physiotherapy	45	3	8
Treadmill training	30	3	4
Dance	60	2	10
Tai chi	60	2	24
Trigger point massage	45	2	8
Cueing	30	3	3
Complex motor sequences	30	3	3

6.2 Risks

Ernst et al (2024) reviewed 154 controlled studies of exercise interventions for people with Parkinson's disease. They found only 85 studies reported on presence or absence of adverse events. Falls were reported in 18 studies and pain in 10 studies. The authors note "although our review pointed out the difficulties in synthesizing the evidence on the comparative safety of different types of physical exercise, our results are consistent with previous research suggesting that, in general, physical exercise seems to be relatively safe" (p.64)

Osborne et al (2022) reviewed risks reported in studies of aerobic exercise, resistance training, balance training, flexibility training, external cueing, community-based exercise, gait training, task specific training, and a behaviour change approach. They note that there is minor risk if standard safety procedures are in place. People prescribed exercise should be screened for heart issues or other health concerns that would preclude moderate to high intensity exercise. If intensity and duration of exercise is increased, it should be done gradually to prevent injury. Minor musculoskeletal injuries were reported in studies of aerobic exercise, but these resolved. Falls and other adverse effects were reported in some studies, though no study

reported a more significant rate of adverse effects in the intervention group compared to the control group.

6.3 Stage of progression

Li et al (2023) suggest that exercise interventions are beneficial for people at advanced stages of Parkinson's disease to maintain function and health. However, this suggestion was not based on the results of their review, which found no evidence that exercise could limit progression of symptoms for people at advanced stages.

Other reviews have also been unable to determine whether exercise interventions are effective or safe for people at advanced at stages of Parkinson's progression (stages 4 or 5 of the Hoehn & Yahr scale). Ernst et al (2024) reviewed 154 studies and found most studies included participants at stages 1 – 3. No studies included participants at stage 5, while only 17 studies included participants at stage 4. Therefore, the authors note that their results may not apply to people at advanced stages of Parkinson's disease progression.

For most physiotherapy interventions reviewed by Osborne et al (2022), studies supporting the intervention focussed on mostly those with mild to moderate symptoms covering Hoehn & Yahr stages 1 to 3. Studies investigating external cueing and resistance, balance and flexibility training included participants at stages 1 to 4. None of the recommendations made by Osborne et al are relevant to people showing advanced stage 5 symptoms.

7. Multiple Sclerosis

7.1 Frequency and duration

A 2019 systematic review of clinical practice guidelines for exercise interventions for people with Multiple Sclerosis found consistent dosage recommendations for aerobic and resistance training:

> The literature we summarized consistently indicated that moderate-intensity aerobic training should be performed 2 to 3 days per week in 10- to 40-minute bouts. By achieving these guidelines, people with MS can potentially improve their cardiovascular fitness, mobility and symptoms of fatigue and depression. This should be complemented by 2 to 3 days of weekly resistance training, from which anticipated benefits could include: improved strength, balance, mobility, performance of activities of daily living, and symptoms of fatigue (Kim et al, 2019, p.9).

These recommendations may be based on a combination of experimental evidence and clinical judgement. However, considering the difficulty of deriving optimal dosage levels from the current evidence, it is likely that the recommendations in Kim et al represent a professional consensus rather than an evidence-based conclusion (Taul-Madsen et al, 2021; Edwards & Pilutti, 2017).

Corrini et al (2023) reviewed 20 randomised controlled trials looking at the effect of balance training programs for people with Multiple Sclerosis. They found high quality evidence that physiotherapy targeting balance has a moderate effect on improving balance as measured by the Berg Balance Scale. In addition, their meta-analysis was able to show that sessions lasting 40 minutes or longer produced a significant and clinically meaningful improvement in balance scores, while sessions lasting under 40 minutes did not produce statistically significant results. The authors concluded that:

> intense treatments lasting at least 40 [minutes] were associated with a better and more clinically meaningful improvement, and greater results can be reached when rehabilitation is provided over a short period (duration) and for a few sessions per week (frequency) (Corrini et al, 2023, p.20).

7.2 Risks

Learmonth et al (2023) searched for information on relapse and adverse events after exercise interventions for people with Multiple Sclerosis. They reviewed 40 randomised controlled trials including 1780 participants. The authors found no significant difference in adverse events between exercise intervention and comparison groups. The analysis

> did not reveal any significant variability in risk of exercise training across the potentially important factors of exercise type, delivery style (e.g. supervised, independent or remotely supervised), participant disability level or the prescription of exercise consistent with minimal exercise guidelines for persons with MS (Learmonth, 2023, p.1624).

While exercise interventions are generally considered safe for people with Multiple Sclerosis, safety precautions and modifications may be required depending on the needs of the individual. A 2019 systematic review of guidelines produced the following advice:

> An exercise prescription for people with MS should promote a safe and individualized exercise regimen. Thus, before prescribing an exercise routine, MS specific symptoms/characteristics (i.e., fatigue and heat sensitivity) should be identified and discussed, and the exercise prescription should include appropriate modifications. For example, individuals with high heat sensitivity should exercise in a cool environment, and a cooling fan should be readily available for the person during the exercise sessions. When individuals experience symptom exacerbation, either daily variation in symptoms or relapse, the exercise program may require modification or be temporarily discontinued until the symptoms are stable. Risk of falling should be considered for individuals with MS, and individuals with high risk of falls should perform both aerobic and strength exercises in a seated position (e.g., recumbent bike, weight machines) and under supervision (Kim et al, 2019, p.6)

7.3 Stage of progression

Learmonth et al (2023) did not find any significant difference in risk or safety of exercise interventions between levels of disability. However, it should also be noted that participants with advanced stages of MS were minimally represented in the studies reviewed. Of 40 randomised controlled trials, only 3 were focussed on people with severe symptoms of Multiple Sclerosis. In fact, most evidence for the efficacy of exercise intervention for people with Multiple Sclerosis lacks generalisability for people with severe symptoms (Corrini et al, 2023; Taul-Madsen et al, 2021; Kim et al, 2019; Edwards & Pilutti, 2017).

Two systematic reviews have examined the effectiveness of physiotherapy or exercise interventions in people with Multiple Sclerosis (Binshalan et al, 2022; Edwards & Pilutti, 2017). A 2017 review found limited and very low certainty evidence that exercise interventions could improve fitness, function, balance, fatigue, mood and quality of life (Edwards & Pilutti, 2017). The authors also suggest exercise interventions are safe for people with severe symptoms. More recently, Binshalan et al (2022) found low quality evidence that robot assisted gait therapy may be effective at improving walking speed and endurance in people with severe symptoms of Multiple Sclerosis. The authors speculate on possible reasons robot assisted gait therapy may be more effective than other modes of physiotherapy or exercise intervention:

> Appropriate PT intervention programs must be tailored to the patient's abilities with sufficient stimulus to push present competence to produce effect [49]. Therefore, it possible that RAGT is less demanding for severely disabled pwMS, who might not be able to complete other forms of PT effectively (p.13).

8. Muscular dystrophy

8.1 Frequency and duration

Hammer et al (2022) is the most recent systematic review of physiotherapy or exercise interventions for people with muscular dystrophy. They reviewed 12 studies with 282 participants and found exercise intervention may improve strength and endurance for people with MD. No conclusions regarding frequency, duration or intensity were possible with the available evidence.

A 2019 Cochrane review of exercise training in muscle disease (including MD), notes:

> The most effective dose of exercise for people with muscle diseases is currently unknown, making it difficult to prescribe exercise in this population. This is reflected in the large variation in the frequency, duration and intensity of exercise prescribed (Voet et al, 2019, p.42).

8.2 Risks

The most recent review of physiotherapy or exercise interventions for MD noted that none of the studies included in the review adequately reported on adverse events. However, the authors noted that "intensive eccentric muscle exercise, where the muscle is both activated and lengthened, in addition to high-resistance exercise, may exacerbate muscle damage and should be avoided" (Hammer et al, 2022, p.2).

Voet et al (2019) report no evidence of safety concerns in appropriately structured exercise programmes, though they also note that "included studies were small and the evidence was largely low or low certainty; therefore, we can make no definitive statements regarding safety" (p.42).

8.3 Stage of progression

No studies were able to discriminate benefits or risks of exercise based on severity of symptoms or stage of progression.

9. References

Binshalan, T., Nair, K. P. S., & McNeill, A. (2022). The Effectiveness of Physiotherapy Interventions for Mobility in Severe Multiple Sclerosis: A Systematic Review and Meta-Analysis. *Multiple sclerosis international*, 2022, 2357785. https://doi.org/10.1155/2022/2357785

Baumann, A. N., Curtis, D. P., Chen, M., & Baldwin, K. D. (2023a). The Impact of the Addition of a Physical Therapy Assistant to the Treatment Team for Management of Neck Pain: A Retrospective Analysis of Outpatient Physical Therapy Clinics. *Cureus*, *15*(7), e42751. https://doi.org/10.7759/cureus.42751

Baumann, A. N., Indermuhle, T., Oleson, C. J., Callaghan, M. E., Rogers, H., Pennacchio, C., Baldwin, K. D., & Leland, J. M., 3rd (2023b). Clinical Outcomes Associated With the Addition of a Physical Therapist Assistant to a Rehabilitation Team When Treating Musculoskeletal Shoulder Pain in the Outpatient Setting: A Retrospective Cohort Study. *Cureus*, *15*(7), e42680. https://doi.org/10.7759/cureus.42680

Corrini, C., Gervasoni, E., Perini, G., Cosentino, C., Putzolu, M., Montesano, A., Pelosin, E., Prosperini, L., & Cattaneo, D. (2023). Mobility and balance rehabilitation in multiple sclerosis: A systematic review and dose-response meta-analysis. *Multiple sclerosis and related disorders*, 69, 104424. https://doi.org/10.1016/j.msard.2022.104424

Edwards, T., & Pilutti, L. A. (2017). The effect of exercise training in adults with multiple sclerosis with severe mobility disability: A systematic review and future research directions. *Multiple sclerosis and related disorders*, 16, 31–39. https://doi.org/10.1016/j.msard.2017.06.003

El Hayek, M., Lobo Jofili Lopes, J. L. M., LeLaurin, J. H., Gregory, M. E., Abi Nehme, A. M., McCall-Junkin, P., Au, K. L. K., Okun, M. S., & Salloum, R. G. (2023). Type, Timing, Frequency, and Durability of Outcome of Physical Therapy for Parkinson Disease: A Systematic Review and Meta-Analysis. *JAMA network open*, *6*(7), e2324860. https://doi.org/10.1001/jamanetworkopen.2023.24860

Ernst, M., Folkerts, A. K., Gollan, R., Lieker, E., Caro-Valenzuela, J., Adams, A., Cryns, N., Monsef, I., Dresen, A., Roheger, M., Eggers, C., Skoetz, N., & Kalbe, E. (2024). Physical exercise for people with Parkinson's disease: a systematic review and network meta-analysis. *The Cochrane database of systematic reviews*, *4*(4), CD013856. https://doi.org/10.1002/14651858.CD013856.pub3

Grimes, D., Fitzpatrick, M., Gordon, J., Miyasaki, J., Fon, E. A., Schlossmacher, M., Suchowersky, O., Rajput, A., Lafontaine, A. L., Mestre, T., Appel-Cresswell, S., Kalia, S. K., Schoffer, K., Zurowski, M., Postuma, R. B., Udow, S., Fox, S., Barbeau, P., & Hutton, B. (2019). Canadian guideline for Parkinson disease. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne*, *191*(36), E989–E1004. https://doi.org/10.1503/cmaj.181504

Hammer, S., Toussaint, M., Vollsæter, M., Nesbjørg Tvedt, M., Drange Røksund, O., Reychler, G., Lund, H., & Andersen, T. (2022). Exercise Training in Duchenne Muscular Dystrophy: A Systematic Review and Meta-Analysis. *Journal of rehabilitation medicine*, 54, jrm00250. https://doi.org/10.2340/jrm.v53.985

Keus, S., Munneke, M., Graziano, M., Paltamaa, J., Pelosin, E., Domingos, J., ... & Bloem, B. (2014). *European physiotherapy guideline for Parkinson's disease*. The Netherlands: KNGF/ParkinsonNet.

Kim, Y., Lai, B., Mehta, T., Thirumalai, M., Padalabalanarayanan, S., Rimmer, J. H., & Motl, R. W. (2019). Exercise Training Guidelines for Multiple Sclerosis, Stroke, and Parkinson Disease: Rapid Review and Synthesis. *American journal of physical medicine & rehabilitation*, *98*(7), 613–621. https://doi.org/10.1097/PHM.0000000000001174

Kyriakatis, G. M., Lykou, P. M., Dimitriadis, Z., & Besios, T. (2023). Efficacy of remote exercise and physiotherapy programs on depressive symptoms in people with multiple sclerosis - A systematic review and meta-analysis. *Multiple sclerosis and related disorders*, 79, 105067. https://doi.org/10.1016/j.msard.2023.105067

Lau, B., March, M. K., Harmer, A. R., Caruana, S., Mahony, C., & Dennis, S. (2024). Experiences of Boosting Inpatient Exercise After HipFracture Surgery Using An Alternative Workforce - A Qualitative Study. *BMC geriatrics*, *24*(1), 183. https://doi.org/10.1186/s12877-024-04756-1

Learmonth, Y. C., P Herring, M., Russell, D. I., Pilutti, L. A., Day, S., Marck, C. H., Chan, B., Metse, A. P., & Motl, R. W. (2023). Safety of exercise training in multiple sclerosis: An updated systematic review and meta-analysis. *Multiple sclerosis (Houndmills,*

Basingstoke, England), *29*(13), 1604–1631. https://doi.org/10.1177/13524585231204459

Meng, L., Li, X., Li, C., Tsang, R. C., Chen, Y., Ge, Y., & Gao, Q. (2020). Effects of exercise in patients with amyotrophic lateral sclerosis: a systematic review and meta-analysis. *American Journal of Physical Medicine & Rehabilitation*, *99*(9), 801-810. https://doi.org/10.1097/PHM.0000000000001419

Motor Neuron Disease Australia. (2021). *Physical Activity and MND*. https://www.mndaustralia.org.au/mnd-connect/information-resources/physical-activity-and-mnd

National Institute of Health and Care Excellence. (2017). *Parkinson's disease in adults: diagnosis and management* [NG71]. https://www.nice.org.uk/guidance/ng71

O'Callaghan, G., Murray, D. & Vance, R. (2014). Guidelines for the physiotherapy management of Motor Neuron Disease. Irish Hospice Foundation. https://d2khofxhx95v1k.cloudfront.net/b1fdb917f1fea268a7a1b7b502dcd172.pdf

Osborne, J. A., Botkin, R., Colon-Semenza, C., DeAngelis, T. R., Gallardo, O. G., Kosakowski, H., Martello, J., Pradhan, S., Rafferty, M., Readinger, J. L., Whitt, A. L., & Ellis, T. D. (2022). Physical Therapist Management of Parkinson Disease: A Clinical Practice Guideline From the American Physical Therapy Association. *Physical therapy*, *102*(4), pzab302. https://doi.org/10.1093/ptj/pzab302

Papadopoulou, M., Papapostolou, A., Dimakopoulos, R., Salakou, S., Koropouli, E., Fanouraki, S., Bakola, E., Moschovos, C., & Tsivgoulis, G. (2024). Non-Pharmacological Interventions on Pain in Amyotrophic Lateral Sclerosis Patients: A Systematic Review and Meta-Analysis. *Healthcare (Basel, Switzerland)*, *12*(7), 770. https://doi.org/10.3390/healthcare12070770

Sarigiovannis, P., Foster, N. E., Jowett, S., & Saunders, B. (2023). Developing a best practice framework for musculoskeletal outpatient physiotherapy delegation: the MOPeD mixed-methods research study protocol. *BMJ open*, *13*(3), e072989. https://doi.org/10.1136/bmjopen-2023-072989

Sarigiovannis, P., Foster, N. E., Jowett, S., & Saunders, B. (2022). Delegation of workload from musculoskeletal physiotherapists to physiotherapy assistants/support workers: A UK online survey. *Musculoskeletal science & practice*, 62, 102631. https://doi.org/10.1016/j.msksp.2022.102631

Sarigiovannis, P., Jowett, S., Saunders, B., Corp, N., & Bishop, A. (2021). Delegation by Allied Health Professionals to Allied Health Assistants: a mixed methods systematic review. *Physiotherapy*, 112, 16–30. https://doi.org/10.1016/j.physio.2020.10.002

Snowdon, D. A., Wang, Y. T., Callisaya, M. L., Collyer, T. A., Jolliffe, L., Johns, N., Vincent, P., Pragash, N., & Taylor, N. F. (2024). Staying Active with Multimorbidity In Acute hospital settings (StAMInA) trial: protocol for a feasibility randomised controlled trial of allied

health assistant mobility rehabilitation for patients with multimorbidity. *BMJ open*, *14*(1), e078843. https://doi.org/10.1136/bmjopen-2023-078843

Snowdon, D. A., King, O. A., Dennett, A., Pinson, J. A., Shannon, M. M., Collyer, T. A., Davis, A., & Williams, C. M. (2022). Delegation of patient related tasks to allied health assistants: a time motion study. *BMC health services research*, *22*(1), 1280. https://doi.org/10.1186/s12913-022-08642-7

Snowdon, D. A., Vincent, P., Callisaya, M. L., Collyer, T. A., Wang, Y. T., & Taylor, N. F. (2021). Feasibility of allied health assistant management of people with acute hip fracture: protocol for a feasibility randomised controlled trial. *BMJ open*, *11*(11), e054298. https://doi.org/10.1136/bmjopen-2021-054298

Snowdon, D. A., Storr, B., Davis, A., Taylor, N. F., & Williams, C. M. (2020). The effect of delegation of therapy to allied health assistants on patient and organisational outcomes: a systematic review and meta-analysis. *BMC health services research*, *20*(1), 491. https://doi.org/10.1186/s12913-020-05312-4

Taul-Madsen, L., Connolly, L., Dennett, R., Freeman, J., Dalgas, U., & Hvid, L. G. (2021). Is Aerobic or Resistance Training the Most Effective Exercise Modality for Improving Lower Extremity Physical Function and Perceived Fatigue in People With Multiple Sclerosis? A Systematic Review and Meta-analysis. *Archives of physical medicine and rehabilitation*, *102*(10), 2032–2048. https://doi.org/10.1016/j.apmr.2021.03.026

Voet, N. B., van der Kooi, E. L., van Engelen, B. G., & Geurts, A. C. (2019). Strength training and aerobic exercise training for muscle disease. *The Cochrane database of systematic reviews*, *12*(12), CD003907. https://doi.org/10.1002/14651858.CD003907.pub5

Zhou, B., Wei, J., Zhang, Y., Liu, Y., Shan, S., Ye, S., Li, B., Fan, D., & Luo, Y. (2022). Different observation period of exercise training in amyotrophic lateral sclerosis patients: A meta-analysis. *Frontiers in neurology*, 13, 986882. https://doi.org/10.3389/fneur.2022.986882

Research – List of Rapidly Progression Conditions

Brief	Generate a list of rapidly degenerative conditions. As part of the Independent Assessment project - Personal Budget tool (PBT) the Scheme actuary asked TAB for a list of rapidly degenerating conditions for participants whom would be in the NDIS. TAB SMEs were able to identify some - motor neuron disease, Some types of muscular dystrophy Some types of Spinal Muscular Atrophy. However it is likely there are some chromosomal disorders or medical conditions that result in a disability that also have rapid deterioration.
Date	19/03/2021
Requester(s)	Jane s47F - personal (Assistant Director – TAB)
Researcher	Jane s47F - personal priva - Research Team Leader (TAB)
Cleared	N/A

Please note:

The research and literature reviews collated by our TAB Research Team are not to be shared external to the Branch. These are for internal TAB use only and are intended to assist our advisors with their reasonable and necessary decision-making.

Delegates have access to a wide variety of comprehensive guidance material. If Delegates require further information on access or planning matters they are to call the TAPS line for advice.

The Research Team are unable to ensure that the information listed below provides an accurate & up-to-date snapshot of these matters.

1 Contents

2 List of rapidly progressing conditions

This list was compiled using a combination of search terms in Google such as:

Rapid*/fast

OR

Progress*/degenerat*

OR

Condition*/disease*/diagnos*

Every effort was made to locate conditions considered rapidly progressing (change in condition/circumstance in <12 months), however, this list should not be considered exhaustive as some conditions may have been overlooked. Any condition that made mention of "slow" progression was not included.

- Motor Neurone Disease (MND)/Amyotrophic lateral sclerosis (ALS)/Lou Gehrig's Disease
- Spinal Muscular Atrophy – *Type 1 & 2 are rapidly progressing*
- Duchenne muscular dystrophy (DMD) – *many individuals rapidly progress*
- Progressive supranuclear palsy
- Primary progressive aphasia – *rapid progression, usually live 3-12 years after diagnosis*
- transmissible spongiform encephalopathies/Prion disease
    - Creutzfeldt-Jakob Disease (CJD)
    - Variant Creutzfeldt-Jakob Disease (vCJD)
    - Gerstmann-Straussler-Scheinker Syndrome
    - Fatal Familial Insomnia
- GM1 gangliosidosis
- Canavan disease
- X-linked adrenoleukodystrophy
- Rett syndrome – Stage 1 & 2 progress rapidly