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?

How do other Australian insurance schemes and funding bodies approach the funding of on-going and time-limited manual therapies?

Date: 08/08/2023

Requestor: Karyn s22(1)(a)(ii) - irrelevant

Endorsed by:

Researcher: Aaron s22(1)(a)(ii) - irrelevant ma

Cleared by: Stephanie s22(1)(a)(ii) - irrelevant mat

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 and how this intervention is approached by Australian public funding schemes.

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 (3.1.2 Intervention). Manual therapy may also address functional difficulties including impairment, activity limitation or participation restrictions (3.1.4 Outcomes) for people experiencing 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 (3.1.1 Population).

2.1 Efficacy and clinical practice

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 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.

2.2 Funding approaches

Funding for manual therapy in Australian public or insurance schemes varies based on funding limits and other conditions.

Funding limits can relate to cost or length of treatment. Policy and practice of service systems can vary by proportion of the therapy that is funded, the standard rate of pay per session, total funding allowed, or total number of sessions permitted. None of the service systems reviewed describe limits on number of sessions or duration of treatment that are particular to manual therapy providers. That is, while some insurance scheme clients may be funded for a set length of time (e.g., 2 years, 5 years), this limitation applies to all health or medical expenses and not just manual therapy funding. Only Medicare prescribes strict limits on the number of allowable sessions. Other service systems address will address the request on a case-by-case basis. Refer to 6.2 Funding limits for further details.

Other funding conditions relate to the provider and the provider's practice. All the service systems reviewed permit manual therapy in the form of physiotherapy, chiropractic or osteopathy in some form. Some also fund massage delivered by providers not eligible for registration with the Australian Health Practitioner Regulation Agency (AHPRA). Some service systems do not allow simultaneous funding of multiple manual therapy interventions (e.g., from a physiotherapist, chiropractor and osteopath). Generally, service systems do not explicitly state policy related to specific manual therapy techniques. However, different rules may apply to funding of massage depending on who provides the therapy and how it is integrated into a broader treatment program. Refer to 6.1 Practice restrictions and funding conditions for further details.

Policy and practice is generally guided by evidence-based practice and most service systems endorse the Clinical Framework for the Delivery of Health Services (Clinical Framework). The Department of Veteran Affairs explicitly states that funding is not provided to osteopaths or chiropractors for non-musculoskeletal conditions. Other service systems may impose practice restrictions in line with how their service interprets evidence-based practice guidelines. Refer to 6.1.1 The Clinical Framework for the Delivery of Health Services for a discussion of how the Clinical Framework is applied.

2.3 Other TAB research

For further examination of the evidence-base for chiropractic, refer to RES 264 Efficacy of chiropractic treatment.

RES 276 Sensory based therapy contains 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 primarily explored through discussion of clinical practice guidelines and systematic reviews of manual therapy interventions.

3.1.1 Population – people experiencing 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).

3.1.2 Intervention – 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 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 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.

3.1.3 Comparison – active exercise

Where possible, this paper will compare the efficacy of manual therapy with active exercise including therapist-lead or supervised training and home- or gym-based exercise programs. However all comparisons will be considered.

3.1.4 Outcomes – functional improvement

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).

National Disability Insurance Scheme (Supports for Participants) Rules 2013 signals the NDIA's focus on activity limitations and participation restrictions (s.4.1-4.6). 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

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 showing efficacy is 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. There was notable heterogeneity between 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 to 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).

5.1.1 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 instance, the NICE guideline for osteoarthritis provides a rationale for their 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).

5.1.2 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 programme 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. Australian government funding bodies

This section describes the approach that different Australian government funding bodies or public insurance schemes take in the funding of manual therapy. This section surveys the available information but will not cover every scheme or funding source available. Refer to 6.1 List of Australian government funding bodies for a more comprehensive list of public insurance schemes and funding bodies.

More detail is provided in 6. Features of Australian government funding bodies.

6.1 Practice restrictions and funding conditions

Funding bodies may specify what therapies are covered, who can offer the treatment and how it should be delivered. Refer to 6.2 Conditions for manual therapy funding in some Australian funding bodies for further details.

Most funding bodies reviewed can fund manual therapy when provided by AHPRA registered allied health professionals such as physiotherapists, osteopaths and chiropractors. One exception is Medicare's subsidy for health services for young people with neurodevelopmental conditions. Under this scheme, physiotherapy is eligible for subsidy but not chiropractic or osteopathy (Department of Health and Aged Care, 2023). DVA specifies that chiropractors and

osteopaths must only treat disorders of the musculo-skeletal system (DVA, 2021b-c) but this restriction is not noted for physiotherapists (DVA, 2021d).

Some schemes fund non-AHPRA registered providers. Comcare, WorkSafe Victoria and icare will consider funding massage that is delivered by non-AHPRA eligible provider such as massage therapists, myotherapists, traditional medicine practitioners and others (SIRA, 2023b; Comcare, 2023a; WorkSafe Victoria, 2022b). DVA, WorkSafe Queensland and TAC will not consider manual therapies delivered by massage therapists, masseurs, myotherapists or other non-approved providers (TAC, 2023a-c; WorkSafe Queensland, 2021; DVA, 2021a).

For the most part, funding bodies do not exclude particular manual therapy techniques or strategies provided by qualified and registered therapists (e.g., adjustment, manipulation, mobilisation, massage etc.). WorkSafe Queensland further specify that they will fund massage as a part of a course of treatment, but not as a stand-alone treatment (WorkSafe Queensland, 2021a).

Several schemes mention the use of concurrent therapy, that is, similar modalities offered at the same time for the same condition such physiotherapy, chiropractic and osteopathy. DVA and WorkSafe Victoria note that they will not fund concurrent treatment (DVA, 2022b; WorkSafe Victoria, 2023d-f). TAC and icare note that concurrent treatment is discouraged, though might be funded if clinically necessary (TAC, 2023a-c; SIRA, 2021b; Insurance and care, 2021). For NSW's Lifetime Care, concurrent treatment may be approved if there is:

- reasonable clinical justification
- an overall coordinated plan
- close communication between treatment providers
- closely aligned goals between treatment providers
- written information outlining the context of request
- evidence that providers are treating different conditions to achieve different treatment goals (Insurance and care, 2021, p.61).

6.1.1 The Clinical Framework for the Delivery of Health Services

The Clinical Framework for the Delivery of Health Services (Clinical Framework) is a publication from Victoria's Transport Accident Commission (TAC) and WorkSafe Victoria. It is a principle-based framework setting out expectations for health care providers serving clients in workers' compensation or transport accident schemes (Health Services Group, 2013).

The principles of the Clinical Framework are:

1. Measure and demonstrate the effectiveness of treatment
2. Adopt a biopsychosocial approach
3. Empower the injured person to manage their injury

4. Implement goals focused on optimising function, participation and return to work
5. Base treatment on the best available research evidence (Health Services Group, 2013).

The Clinical Framework has been endorsed by all Australian state and federal governments and most injury insurance and general health schemes. There are two exceptions for which the relationship to the Clinical Framework is more ambiguous:

- **Queensland's National Injury Insurance Scheme** (NIISQ) is a transport accident scheme created in 2016 after the Clinical Framework was published. NIISQ treatment guidelines endorse the Clinical Framework. However, the guidelines are still in draft form undergoing a period of consultation and so it is assumed the official endorsement depends on the guidelines being finalised (NIISQ, 2023).
- **Department of Veterans' Affairs** is mentioned on the list of federal government organisations supporting the Clinical Framework (Health Services Group, 2013; TAC, 2012). However, DVA does not mention the Clinical Framework or its implementation on their website or in their publications. It is therefore not clear how DVA implements the Clinical Framework or whether they continue to support it.

While the Clinical Framework is widely endorsed there are implementation differences across workers' compensation or transport accident schemes. Most schemes at least encourage manual therapy providers to incorporate the principles of the Clinical Framework in their practice (WorkSafe Queensland, 2020b; WorkCover WA, 2016). Some go further and specify that providers must adopt the Clinical Framework in their practice (WorkSafe Victoria, 2023d-f; Comcare, 2023a; TAC, 2020).

Most scheme legislation restricts funding to supports that are reasonable and necessary (or reasonable, necessary and reasonable, reasonably necessary, reasonable and appropriate, appropriate etc.) (WorkSafe Queensland, 2023b; 2022a; WorkSafe Victoria, 2022; WorkCover WA, 2021b; TAC, 2020; Comcare, 2017a-b; Motor Accident Insurance Commission, 2013; *Safety, Rehabilitation and Compensation (Defence-related Claims) Act 1988*; *Military Rehabilitation and Compensation Act 2004*). Both Comcare and icare explicitly use the Clinical Framework to elaborate their definition of reasonableness (Insurance & care NSW, 2021; Comcare, 2017a). WorkSafe Victoria (2023g) and TAC (2020) also incorporate the Clinical Framework in their funding approval process.

6.2 Funding limits

For the majority of schemes, funding is limited by liability decisions made by the administering organisation. Funding for manual therapy may also be limited by caps on number of sessions, duration of coverage, cost of each session or total funding.

6.2.1 Limit on duration of treatment

Of the service systems reviewed, only Medicare places a strong limit on the number of allowable sessions. The Chronic Disease Management scheme subsidises up to 5 sessions of allied health therapy per year. The Complex Neurodevelopmental Disability scheme subsidises up to 20 sessions of allied health therapy in a person's lifetime.

Some schemes impose a limit on the number of sessions funded before formal approval is required. This limit does not impose a limit on the total number of sessions which might be deemed reasonable and necessary. Workers Care in NSW allows 8 visits with a physiotherapist, chiropractor or osteopath before pre-approval is required (SIRA, 2023; SIRA, 2021). DVA funds allied therapy in treatment cycles of 12 sessions or 1 year, whichever finishes first (DVA, 2022c), at which point a new treatment plan is required. Comcare allows 5 initial sessions of physiotherapy before a treatment plan is required (Comcare, 2023c).

NSW's Workers' Care scheme limits funding based on percentage of assessed impairment. Participants in the scheme with no permanent impairment or an assessed permanent impairment under 10% are eligible for support for up to 2 years. Participants in the scheme with an assessed permanent impairment of 11-20% are eligible for support for up to 5 years. If assessed permanent impairment is over 20%, participants are entitled to support for their lifetime (Insurance and care, 2023).

6.2.2 Limit on cost of treatment

A number of schemes impose an upper limit on the cost of each treatment session. DVA and icare's Workers' Care do not permit providers to charge more than the established fee (SIRA, 2023a; DVA, 2023a; 2022a-b). Participants are likely to pay a gap with other services (Department of Health and Aged Care, 2023; WorkSafe Queensland 2023a; 2022b-c; WorkCover WA, 2022a-c; TAC, 2023a; WorkSafe Victoria, 2023a-c). Refer to 6.3 Manual therapy fee schedules for some Australian funding bodies for further details.

WorkCover WA lists a total funding cap that participants in the scheme cannot exceed. In addition, WA's *Workers' Compensation and Injury Management Act 1981* prescribes a percentage limit of the total funding cap that can be used for medical expenses. Currently the cap for health services is $73,197, which is 30% of the total funding cap. Although participants with an impairment level over 15% may be entitled to an increase funding cap for medical expenses by $250,000 (WorkCover WA, 2021a). As of July 2023, new legislation is being debated in WA's Legislative Council which will raise the medical expenses cap from 30% to 60% of the total funding cap, increasing it to $146,395 (WorkCover WA, 2023a; Parliament of Western Australia, 2023).

7. Features of Australian government funding bodies

7.1 List of Australian government funding bodies

Jurisdiction	Transport Accident	Workers' Compensation	General health
National		Comcare Seacare Department of Veterans Affairs	Medicare Department of Veterans Affairs MyAgedCare
ACT	Lifetime Care and Support Scheme	WorkSafe ACT	
NSW	icare Lifetime Care icare CTP Care	Icare Workers' Care	
NT	Motor Accidents Compensation Commission	WorkSafeNT	
QLD	National Injury Insurance Scheme, Queensland Motor Accident Insurance Scheme	WorkSafe Queensland	
SA	Lifetime Support Scheme	ReturnToWorkSA	
Tas	Motor Accidents Insurance Board	Worksafe Tasmania	

Jurisdiction	Transport Accident	Workers' Compensation	General health
Vic	Transport Accident Commission	WorkSafe Victoria	
WA	Catastrophic Injuries Support Scheme	WorkCover WA	

7.2 Conditions for manual therapy funding in some Australian funding bodies

Funding body	Manual therapy can be provided by	Practice conditions	Other conditions
Medicare – Chronic Disease Management	• AHPRA registered physiotherapists, chiropractors, osteopaths		• User must have chronic condition likely to be present for 6 months • User must have GP Management Plan with Team Care Arrangement
Medicare – Complex Neurodevelopmental Disability	• AHRPA registered physiotherapists		• User must be under 25 years old with a complex neurodevelopmental disorder or another eligible disability
Department of Veterans' Affairs	• AHPRA registered physiotherapists, chiropractors, osteopaths	• Chiropractors and osteopaths must only treat disorders of the musculoskeletal system • Will not fund concurrent treatment • Osteopaths, chiropractors and physiotherapists cannot	

Funding body	Manual therapy can be provided by	Practice conditions	Other conditions
		provide services on the same day as exercise physiologist • Implementation of the Clinical Framework is unclear	
Comcare	• AHPRA registered physiotherapists, chiropractors, osteopaths • Massage therapists, masseurs	• Treatment must be delivered in line with the Clinical Framework	• Treatment request must be reasonable • Treatment request must be consistent with The Clinical Framework
WorkCover Western Australia	• AHPRA registered physiotherapists, chiropractors, osteopaths • Massage therapists	• Massage therapists • Providers are encouraged to deliver treatment in line with the Clinical Framework	• Treatment request must be reasonable
WorkSafe Queensland	• AHPRA registered physiotherapists, chiropractors, osteopaths	• Providers are encouraged to deliver treatment in line with the Clinical Framework	• Treatment request must be reasonable and necessary and of a reasonable cost
WorkSafe Victoria (2022b)	• AHPRA registered physiotherapists, chiropractors, osteopaths • Massage therapists, myotherapists, traditional medicine practitioners who are registered with the appropriate professional organisation	• Treatment must be delivered in line with the Clinical Framework • Massage may only be used to treat musculoskeletal dysfunction • Will not fund concurrent treatment	• Treatment request must be reasonable and necessary • Treatment request must be either consistent with the Clinical Framework or endorsed by recognised body (e.g. Medicare)

Funding body	Manual therapy can be provided by	Practice conditions	Other conditions
icare – Workers' Care	• AHPRA registered physiotherapists, chiropractors, osteopaths • Massage therapists	• Treatment must be delivered in line with the Clinical Framework • Massage may only be used to treat musculoskeletal dysfunction • Concurrent treatment is not recommended, though might be funded if it is clinically necessary	• Treatment request must be reasonably necessary • Treatment request must be consistent with the Clinical Framework
icare – Lifetime Support	• AHPRA registered physiotherapists, chiropractors, osteopaths • Massage therapists	• Treatment must be delivered in line with the Clinical Framework • Concurrent treatment is not recommended, though might be possible if it is clinically necessary	• Treatment request must be reasonable and necessary
Transport Accident Commission	• AHPRA registered physiotherapists, chiropractors, osteopaths	• Treatment must be delivered in line with the Clinical Framework • Concurrent treatment is not recommended, though might be possible if it is clinically necessary	• Treatment request must be reasonable, outcome focussed and consistent with the Clinical Framework

7.3 Manual therapy fee schedules for some Australian funding bodies

The following describes recommended or mandated fees in a selection of Australian funding bodies and insurance schemes. Amounts listed are fees per session.

Funding body	Gap payment	Physiotherapy	Chiropractic	Osteopathy	Notes
Medicare – Chronic Disease Management (Department of Health and Aged Care, 2023)	Yes	$58	$58	$58	
Medicare – Complex Neurodevelopmental Disability (Department of Health and Aged Care, 2023)	Yes	$81.90	nil	nil	Only physiotherapy subsidised
Department of Veterans' Affairs (2023b-d)	No	$70.40 – $88.40	$70.40 –$73.30	$70.40 –$73.30	Upper limit varies by type, location and length of service

Funding body	Gap payment	Physiotherapy	Chiropractic	Osteopathy	Notes
Comcare (2023b; 2017b)	Not known	$66.74 – $245.24 (varies by state and complexity)	$55.03 – $146.78	$135.74 – 175.64	Fee schedule based on Australian Medical Association suggested fees. Suggested upper limit varies by state and complexity. Upper limits are not mandated and costs for individual claims are decided on a case-by-case basis.
WorkCover Western Australia (2022a-c)	Yes	$74.60 – $94.75	$61.20 – $71.35	$88.40	Upper limit varies by type of service and complexity
WorkSafe Queensland (2023a; 2022b-c)	Yes	$97 – $124	$88 – $117	$88 – $117	Upper limit varies by type and length of service

Funding body	Gap payment	Physiotherapy	Chiropractic	Osteopathy	Notes
WorkSafe Victoria (2023a-c)	Yes	$64.09 – $128.21	$55.03 – $94.29	$75.25 – $112.51	Upper limit varies by type of service and complexity
icare – Workers' Care (SIRA, 2023a)	No	$62.10 – $188.30	$62.10 – $188.30	$62.10 – $188.30	Upper limit varies by type of service and complexity
icare – Lifetime Support (SIRA, n.d b; *Motor Accidents (Lifetime Care and Support) Act 2006*)	No	No set fee	No set fee	No set fee	Fee determined on case-by-case basis
Transport Accident Commission (2023a-c)	Yes	$63.64 – $139.90	$54.17 – $94.33	$61.68 – $76.69	Upper limit varies by type of service and complexity

8. 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

Comcare. (2023a). *Allied health professionals*. Australian Government. https://www.comcare.gov.au/service-providers/medical-allied-health/allied-health

Comcare. (2023b). *Rates for medical and allied health treatment*. Australian Government. https://www.comcare.gov.au/service-providers/medical-allied-health/treatment-rates

Comcare. (2023c). *Medical treatment*. Australian Government. https://www.comcare.gov.au/claims/supports-benefits/medical-treatment

Comcare. (2017a). *Applying the Clinical Framework to assess the reasonableness of medical treatment*. Australian Government. https://www.comcare.gov.au/scheme-legislation/src-act/guidance/applying-clinical-framework

Comcare. (2017b). *Appropriate cost of medical treatment*. Australian Government. https://www.comcare.gov.au/scheme-legislation/src-act/guidance/appropriate-cost-medical-treatment

Comcare. (2014). *Early Intervention Report*. Australian Government. https://www.comcare.gov.au/about/forms-pubs/docs/pubs/research/early-intervention-report.pdf

Department of Health and Aged Care. (2023). Medicare benefits schedule book – Category 8. Australian Government. http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Downloads-230701

Department of Veterans' Affairs. (2023a). *DVA arrangements for physiotherapists*. Australian Government. https://www.dva.gov.au/get-support/providers/allied-health-provider-information/dva-arrangements-physiotherapists

Department of Veterans' Affairs. (2023b). *Osteopaths schedule of fees*. Australian Government. https://www.dva.gov.au/sites/default/files/2023-07/osteopathfees.pdf

Department of Veterans' Affairs. (2023c). *Chiropractors schedule of fees*. Australian Government. https://www.dva.gov.au/sites/default/files/2023-07/chirofees.pdf

Department of Veterans' Affairs. (2023d). *Physiotherapists schedule of fees*. Australian Government. https://www.dva.gov.au/sites/default/files/2023-07/physiofees.pdf

Department of Veterans' Affairs. (2022a). *DVA arrangements for osteopaths*. Australian Government. https://www.dva.gov.au/providers/allied-health-provider-information/dva-arrangements-osteopaths

Department of Veterans' Affairs. (2022b). *DVA arrangements for chiropractors*. Australian Government. https://www.dva.gov.au/providers/allied-health-provider-information/dva-arrangements-chiropractors

Department of Veterans' Affairs. (2022c). *Notes for allied health providers - Section 1 - General*. Australian Government. https://www.dva.gov.au/sites/default/files/files/providers/alliedhealth/notes-allied-health-providers-section-1.pdf

Department of Veterans' Affairs. (2022d). *Environmental Scan: Rehabilitation Way Forward*. Australian Government. https://www.dva.gov.au/sites/default/files/2023-05/project-completion-and-implications-report-environmental-scan%E2%80%93rehabilitation-way-forward-2022.pdf

Department of Veterans' Affairs. (2021a). *Alternative therapies*. Australian Government. https://www.dva.gov.au/get-support/health-support/health-services/alternative-therapies

Department of Veterans' Affairs. (2021b). *Notes for allied health providers - Section 2(b) - Chiropractors*. Australian Government. https://www.dva.gov.au/sites/default/files/files/providers/alliedhealth/notes_chiro_2b_2021.pdf

Department of Veterans' Affairs. (2021c). *Notes for allied health providers - Section 2(i) - Osteopaths*. Australian Government. https://www.dva.gov.au/sites/default/files/2023-05/notes_osteo_sec2i.pdf

Department of Veterans' Affairs. (2021d). *Notes for allied health providers - Section 2(j) - Physiotherapists*. Australian Government. https://www.dva.gov.au/sites/default/files/files/providers/alliedhealth/notes_physio_2j_2021.pdf

Department of Veterans' Affairs. (2020). *What a DVA health card covers*. Australian Government. https://www.dva.gov.au/get-support/providers/notes-fee-schedules-and-guidelines/what-dva-health-card-covers

Department of Veterans' Affairs. (2019a). *Osteopathic services*. Australian Government. https://www.dva.gov.au/get-support/health-support/health-services/osteopathic-services

Department of Veterans' Affairs. (2019b). *Chiropractic services*. Australian Government. https://www.dva.gov.au/get-support/health-support/health-services/chiropractic-services

Department of Veterans' Affairs. (2019c). *Physiotherapy services*. Australian Government. https://www.dva.gov.au/get-support/health-support/health-services/physiotherapy-services

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

Health Services Group. (2012). *Clinical Framework for the Delivery of Health Services*. Transport Accident Commission & WorkSafe Victoria. https://www.comcare.gov.au/about/forms-pubs/docs/pubs/claims/clinical-framework-for-the-delivery-of-health-services.pdf

Insurance & care NSW. (2023). *Medical Treatment and Rehabilitation for Workplace Injuries*. https://www.icare.nsw.gov.au/injured-or-ill-people/workplace-injuries/payments/medical-and-rehabilitation-expenses

Insurance & care NSW. (2021). The Lifetime Care and Support Guidelines 2018. https://www.icare.nsw.gov.au/-/media/icare/unique-media/injured-or-ill-people/motor-accident-injuries/guidelines-and-policies/ltcs-guidelines-2018.pdf

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

Military Rehabilitation and Compensation Act 2004 (Cmth). https://www.legislation.gov.au/Details/C2023C00127

Motor Accident Insurance Commission. (2020). *Clinical Framework*. Queensland Government. https://maic.qld.gov.au/for-service-providers/for-health-providers/clinical-framework/

Motor Accident Insurance Commission. (2013). *Guidelines for Compulsory Third Party Rehabilitation Providers*. Queensland Government. https://maic.qld.gov.au/wp-content/uploads/2020/01/MAIC-Guidelines-for-CTP-Rehabilitation-Providers-2020.pdf

Motor Accidents (Lifetime Care and Support) Act 2006 No 16 (NSW). https://legislation.nsw.gov.au/view/whole/html/inforce/current/act-2006-016

National Injury Insurance Scheme, Queensland. (2023). *Treatment, care and support guidelines* [Draft]. Queensland Government. https://niis.qld.gov.au/wp-content/uploads/TCS-guidelines-full-set.pdf

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

Parliament of Western Australia. (2023). *Workers Compensation and Injury Management Bill 2023*. Government of Western Australia. https://www.parliament.wa.gov.au/parliament/bills.nsf/BillProgressPopup?openForm&ParentUNID=C88CE1E7D2B185764825898300316195

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

Safety, Rehabilitation and Compensation (Defence-related Claims) Act 1988 (Cmth). https://www.legislation.gov.au/Details/C2023C00172

Safe Work Australia. (2022). *Summary of Workers' Compensation Scheme Developments in Australia and New Zealand 2022*. Australian Government. https://www.safeworkaustralia.gov.au/sites/default/files/2023-04/summary_of_workers_compensation_arrangements_in_australia_and_new_zealand_2022_report.pdf

Safe Work Australia. (2021). *Comparison of Workers' Compensation Arrangements in Australia and New Zealand 2021*. Australian Government. https://www.safeworkaustralia.gov.au/sites/default/files/2022-10/comparison_of_workers_compensation_arrangements_in_australia_and_new_zealand_2021_swa_edits.pdf

Services Australia. (2022). *Chronic disease individual allied health services Medicare items*. Australian Government. https://www.servicesaustralia.gov.au/chronic-disease-individual-allied-health-services-medicare-items?context=20

State Insurance Regulatory Authority. (2023a, February). *Physiotherapy, Chiropractic and Osteopathy Fees and Practice Requirements*. New South Wales Government. https://www.sira.nsw.gov.au/__data/assets/pdf_file/0005/1122674/Physiotherapy-chiropractic-and-osteopathy-fees-practice-requirements-effective-1-February-2023.pdf

State Insurance Regulatory Authority. (2023b, January). *Massage therapy fees order*. New South Wales Government. https://www.sira.nsw.gov.au/__data/assets/pdf_file/0020/1122671/Massage-therapy-fees-order-effective-1-February-2023.pdf

State Insurance Regulatory Authority. (2021a, March). *Workers compensation guidelines*. New South Wales Government. https://www.sira.nsw.gov.au/workers-compensation-claims-guide/legislation-and-regulatory-instruments/guidelines/workers-compensation-guidelines#part-4

State Insurance Regulatory Authority. (2021b, June). *Workers compensation guide for allied health practitioners*. New South Wales Government. https://www.sira.nsw.gov.au/resources-library/workers-compensation-resources/publications/health-professionals-for-workers-compensation/workers-compensation-guide-for-allied-health-practitioners

State Insurance Regulatory Authority. (n.d. a). Chiropractors. New South Wales Government. https://www.sira.nsw.gov.au/for-service-providers/A-Z-of-service-providers/chiropractors

State Insurance Regulatory Authority. (n.d. b). Physiotherapists. New South Wales Government. https://www.sira.nsw.gov.au/for-service-providers/A-Z-of-service-providers/physiotherapists

State Insurance Regulatory Authority. (n.d. c). Osteopaths. New South Wales Government. https://www.sira.nsw.gov.au/for-service-providers/A-Z-of-service-providers/osteopaths

Transport Accident Commission. (2023a). *Physiotherapy*. Victoria State Government. https://www.tac.vic.gov.au/clients/how-we-can-help/treatments-and-services/services/physiotherapy

Transport Accident Commission. (2023b). *Chiropractic*. Victoria State Government. https://www.tac.vic.gov.au/clients/how-we-can-help/treatments-and-services/services/chiropractic

Transport Accident Commission. (2023c). *Osteopathy*. Victoria State Government. https://www.tac.vic.gov.au/clients/how-we-can-help/treatments-and-services/services/osteopathy

Transport Accident Commission. (2020). *How we make decisions*. Victoria State Government. https://www.tac.vic.gov.au/clients/how-we-can-help/how-we-make-decisions

Transport Accident Commission. (2012). *Collaboration and support for the Clinical Framework*. Victoria State Government. https://www.tac.vic.gov.au/providers/working-with-the-tac/clinical-framework/collaboration-and-support

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

WorkCoverWA. (2023a). *Medical and Health Expenses Compensation*. Government of Western Australia. https://www.workcover.wa.gov.au/wp-content/uploads/2023/02/15.-Medical-and-Health-Expenses-Compensation.pdf

WorkCoverWA. (2023b). *Lifetime Care for Catastrophic Workplace Injuries*. Government of Western Australia. https://www.workcover.wa.gov.au/wp-content/uploads/2023/02/7.-Lifetime-Care-for-Catastrophic-Workplace-Injuries.pdf

WorkCoverWA. (2022a). *Physiotherapists*. Government of Western Australia. https://www.workcover.wa.gov.au/wp-content/uploads/2022/11/Physiotherapy-2022.pdf

WorkCoverWA. (2022b). *Osteopaths*. Government of Western Australia. https://www.workcover.wa.gov.au/wp-content/uploads/2022/11/Osteopaths-2022.pdf

WorkCoverWA. (2022c). *Chiropractors*. Government of Western Australia. https://www.workcover.wa.gov.au/wp-content/uploads/2022/11/Chiropractors-2022.pdf

WorkCoverWA. (2021a). *Workers' Compensation & Injury Management: A Guide for Workers*. Government of Western Australia. https://www.workcover.wa.gov.au/wp-content/uploads/2021/06/Guide-for-Workers-June-2021-WEB.pdf

WorkCoverWA. (2021b). *Frequently Asked Questions*. Government of Western Australia. https://www.workcover.wa.gov.au/health-providers/faqs/

WorkCoverWA. (2016). *Clinical Framework*. Government of Western Australia. https://www.workcover.wa.gov.au/health-providers/clinical-framework/

Workers Compensation Act 1987 No 70 (NSW). https://legislation.nsw.gov.au/view/whole/html/inforce/current/act-1987-070

Workers' Compensation and Injury Management Act 1981 (WA). https://www.legislation.wa.gov.au/legislation/statutes.nsf/main_mrtitle_1090_homepage.html

Workers Compensation and Injury Management Bill 2023 (WA) [Draft]. https://www.parliament.wa.gov.au/Parliament/Bills.nsf/C88CE1E7D2B18576482589830316195/$File/Bill%2B099-2.pdf

WorkSafe Victoria. (2023a). *Physiotherapy services fee schedule*. Victoria State Government. https://www.worksafe.vic.gov.au/physiotherapy-services-fee-schedule

WorkSafe Victoria. (2023b). *Chiropractic services fee schedule*. Victoria State Government. https://www.worksafe.vic.gov.au/chiropractic-services-fee-schedule

WorkSafe Victoria. (2023c). *Osteopathy services fee schedule*. Victoria State Government. https://www.worksafe.vic.gov.au/osteopathy-services-fee-schedule

WorkSafe Victoria. (2023d). *Physiotherapy services policy*. Victoria State Government. https://www.worksafe.vic.gov.au/physiotherapy-services-policy

WorkSafe Victoria. (2023e). *Chiropractic services policy*. Victoria State Government. https://www.worksafe.vic.gov.au/chiropractic-services-policy

WorkSafe Victoria. (2023f). *Osteopathy services information*. Victoria State Government. https://www.worksafe.vic.gov.au/osteopathy-services-information

WorkSafe Victoria. (2023g). *Non-established, new or emerging treatments and services policy*. Victoria State Government. https://www.worksafe.vic.gov.au/non-established-new-or-emerging-treatments-and-services-policy

WorkSafe Victoria. (2022a). *Treatment expenses*. Victoria State Government. https://www.worksafe.vic.gov.au/treatment-expenses

WorkSafe Victoria. (2022b). *Remedial massage services policy*. Victoria State Government. https://www.worksafe.vic.gov.au/remedial-massage-services-policy

WorkSafe Queensland. (2023a). *Physiotherapy Services Table of Costs*. Queensland Government. https://www.worksafe.qld.gov.au/__data/assets/pdf_file/0029/115589/Physiotherapy-Services-1-July-2023.pdf

WorkSafe Queensland. (2023b). *Understanding rehabilitation and return to work terms, roles and responsibilities*. Queensland Government. https://www.worksafe.qld.gov.au/__data/assets/pdf_file/0021/113943/understanding-rehab-and-return-to-work-terms-roles-and-responsibilities.pdf

WorkSafe Queensland. (2022a). *New (non-established) or emerging treatments and services policy*. Queensland Government. https://www.worksafe.qld.gov.au/service-providers/working-with-workcover/new-non-established-or-emerging-treatments-and-services-policy

WorkSafe Queensland. (2022b). *Chiropractic Services Table of Costs*. Queensland Government. https://www.worksafe.qld.gov.au/__data/assets/pdf_file/0026/99026/Chiropractic-Services-1-July-2022.pdf

WorkSafe Queensland. (2022c). *Osteopathy Services Table of Costs*. Queensland Government. https://www.worksafe.qld.gov.au/__data/assets/pdf_file/0024/99033/Osteopathy-Services-1-July-2022.pdf

WorkSafe Queensland. (2021). *Rehabilitation options*. Queensland Government. https://www.worksafe.qld.gov.au/rehabilitation-and-return-to-work/recovering-from-injury-or-illness/starting-your-recovery/rehabilitation-options

WorkSafe Queensland. (2020a). *Treatment and approvals*. Queensland Government. https://www.worksafe.qld.gov.au/service-providers/allied-health-and-return-to-work-providers/treatment-and-approvals

WorkSafe Queensland. (2020b). *Your responsibilities as a provider*. Queensland Government. https://www.worksafe.qld.gov.au/service-providers/working-with-workcover/your-responsibilities-as-a-provider

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 & Argaez, C. (2020). *Manual therapy for chronic, non-cancer back and neck pain: a review of clinical effectiveness*. Ottawa: CADTH.

DOCUMENT 2

Research Request – NAPA Therapy

Brief	• Is intensive therapy (i.e. NAPA) effective and beneficial/will it lead to substantial functional improvement/increase independence in task when compared to other therapeutic approaches? • For children/participants with a disability **from birth** and those that **acquire injury** is there an upper age limit at which further significant improvement/gain from intensive therapy will taper off/cease? • What sorts of benefits can be achieved (or are claimed) through NAPA therapy and as compared to conventional therapy (traditional weekly/fortnightly programs)? • How do NAPA conduct therapy: is it collaborative within disciplines or are participant's still receiving one on one discipline specific therapy? • What level of therapy is needed to maintain results/are results maintained over the long term? • Are intensive suitable for adults? • Is intensive therapy suitable for people with attention/fatigue or cognitive issues (can they focus for duration of intensive 4-5hours, 5 days x 3 weeks ~60-75hours of therapy) • Effectiveness in home program uptake from intensives v traditional therapy? • What indicators used to determine when person has reached their maximal level of function and plateau? • What are the strengths and weaknesses of the NAPA approach to skills acquisition, as compared to other forms of therapy? • What guidelines are available to evaluate or determine when NAPA may be an appropriate approach?
Date	26/11/2020
Requester	Julie s22(1)(a)(ii) - irrelev (Senior Technical Advisor – TAB) Katrin s22(1)(a)(ii) - irre (Assistant Director – TAB)
Researcher	Jane s22(1)(a)(ii) - irreleva (Research Team Leader - TAB)
Cleared by	Jane s22(1)(a)(ii) - irreleva (Research Team Leader - TAB)

Contents

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

Key points

The NAPA centre does not provide any guidelines or specifics around how they determine which interventions are delivered during their "intensive model of therapy," or how they're implemented (multidisciplinary or individual therapists?). The centre promotes that its therapy is "highly effective" and "cutting edge", but without any protocols or published evidence to substantiate these claims it is near impossible to determine whether the program is effective and beneficial. Without any published evidence we can't know:

a) Which diagnosis or ages this intervention is suitable for
b) What the long term results are or adverse effects (if any)
c) What the appropriate dosage/intensity is, or
d) When the patient has reached their maximal level of function

Based on the information provided on the NAPA website it is clear that the Therasuit, SpiderCage and Cuevas Medek Exercises are the key interventions delivered during the intensive program. Current literature does not support these interventions as best practice for cerebral palsy or 'other' neurological conditions.

There are intensive interventions (delivered >3 times a week) for cerebral palsy that are supported by the literature. These include resistance/strength training and interventions for upper limb function such as Constraint Induced Movement Therapy and Bimanual Training. However, these can be delivered in a patient's home or normal environment which makes them highly feasible (and likely cost effective) – rather than attending a clinic for 2-6 hours a day or 3 weeks. Furthermore, systematic reviews comparing conventional therapy (1-2 times a week) to more intensive intervention have reported no clinically meaningful difference.

It is not clear from the NAPA website how patients are followed up after their intensive model of therapy or whether home programs are developed to consolidate any improvements. This is of concern given that home based programs have been shown in the literature to be highly beneficial. The NAPA centre does offer weekly therapy sessions (1 hr) with physiotherapists, occupational therapists and speech pathologists, however, this would only be appropriate for those who live in Sydney, and it is unclear whether these weekly sessions consist of conventional/best practice therapy or those delivered in the intensive model.

Information is provided within the document on neuroplasticity and motor function curves for children with CP. These enable prognosis of gross motor progress across all 5 levels of Gross Motor Function Classification System levels for ages 0 to 15.

Research update (05/03/2021)

A single systematic review and meta-analysis on garment/suit therapy has been added to the literature review. The findings of this study do not change the advice/outcomes of the original research document. Wells, Marquez [1] concluded *"Whilst there is some evidence for the use of garment therapy it is not sufficiently robust to recommend the prescription of garment therapy instead of, or as an adjunct to conventional therapy options".*

What is NAPA?

The Neurological and Physical Abilitation or "NAPA" centre uses what they call the 'Intensive Model of Therapy' (IMOT) when treating children with cerebral palsy (CP) and 'other' neurological disorders. Programs are customised for each patient and vary in time, duration, intensity and tools used. The program usually consists of 2-6 hours of treatment a day, 5 days a week over 3 weeks. This will depend on diagnosis, age, stamina, strengths/weaknesses, and 'other' factors.

The core interventions used are the NeuroSuit and Multifunctional Therapy Unit (SpiderCage) in the intensive therapy programs on children of all ages starting as young as age three. In addition, therapists deliver Cuevas Medek Exercise (CME).

It is claimed that their methods are *"highly effective*" and *"children often advance to the next developmental skill or higher during the three-week program. For example, if a child is using a walker, it is not uncommon for them to gain the strength, balance and ability to walk with crutches."*

The centre also provides

- Weekly therapy - available for physiotherapy, CME/MEDEK, occupational therapy, NeuroSuit (min. 2 hours), and speech therapy. **Fortnightly appointments are not available.**
- VitalStim swallowing therapy
- Developmental feeding therapy
- Speech therapy
- Telehealth – only available to patients with current therapy authorisation with NAPA are eligible

Intensive therapy

Intensive interventions for children with CP refers to the frequency and amount of training, the duration of the training session (minutes or hours), and the duration of the training period (weeks or months). [2, 3] The typical frequency of physical therapy for children with CP in an outpatient setting is not well documented, however, physiotherapy sessions are typically offered 1-2 times per week to young children with CP as reported in Norway, Canada and the US. [2, 4] Various studies investigating intensive therapy/training have typically considered 3 or more sessions per week to constitute 'intensive' compared to conventional treatment. [2, 5]
Although it has been hypothesized that the effectiveness of conventional therapy in children with CP may depend on the dosage of treatment (i.e. with intensive regimens being more effective), this assumption is far from proven. Various systematic reviews and meta-analyses (moderate to high quality) have been published that investigate dosages required to obtain improvements [6] and have compared conventional to intensive therapy [2, 5, 7] (see Table 1 for more in-depth data). The main outcomes from these reviews are as follows:

In relation to upper extremity therapy [6]

- Individual goals can be achieved with a dose of **14–25 hr of practice**, using a combination of face-to-face therapy with practice at home (5.6 hr of face to face and 8.4 hr of home practice) for children over 4 years of age

- A threshold dose of between **30** (OR 3.25 [95% CI 0.9–12.2]) and **40 hrs** (OR 3.75 [95% CI 1.0–14.2]) of practice clinically improves motor ability in the unilateral CP population. The average ratio of therapy: home practice was 70:30.
    - Age–dose relationship suggested younger children **(below the age of 8)** are more likely to improve motor ability.
- No significant difference between intensive (>3x per week) and less frequent. Intensity did not predict success or fail of set goals (OR 1.08 [95% CI 0.2–6.3]).

**It is reasonable to assume that these figures can be transferred to other goal based functional tasks of the lower extremities.*

Comparison of conventional to intensive treatment which target motor and functional skills (delivered by occupational therapist, physical therapist and/or physiotherapist) showed mixed results.

- Myrhaug, Østensjø [2] found that across the majority of studies included in their review, equal improvements were identified between intensive intervention and conventional therapy or between two different intensive interventions.
- Alternatively, Cope and Mohn-Johnsen [7] and Arpino, Vescio [5] found small positive treatment effects in favour of intensive therapy, however, based on the GMFM-88 manual the level of difference is **not considered clinically important/noticeable**. [8]

Taking a closer look at some of the high quality randomised controlled trials included in these meta-analyses it is clear that intensive and standard treatment can both lead to improvements in GMFM. Given that long term follow-up data is sparsely reported, and conventional treatment of 1-2 sessions per week still leads to significant improvements in motor and functional skills it is difficult to justify intensive treatment which is more costly, time consuming and tiring/stressful for children. [5]

In addition, there is research of reasonably low to moderate quality which looks at the potential benefits of intensive strength training. For example, strengthening programs with frequencies of up to 3 times a week demonstrate improvements in gait and function. [9-13] Protocols have more commonly been home/community based [9, 11, 12] and have reported changes in gross motor function [9, 11, 13] cadence, and walking speed. [9, 12, 13] Although these results are positive (and strength training is well recognised as a high quality treatment for CP), many studies did not include a control group to allow for comparison against lower dosages.

Difference between intensive therapy as described in the literature and NAPA therapy

Whilst there are positive findings in the literature (although rarely clinically important or shown to be sustained over the long term) relating to various types of intensive therapy, we must consider how this compares to the method proposed by NAPA.

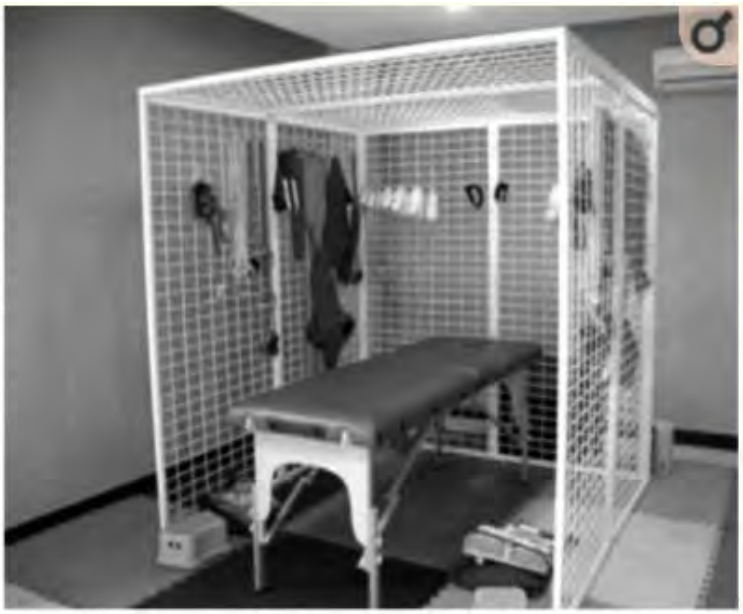
The NAPA program usually consists of 2-6 hours of treatment a day, 5 days a week over 3 weeks. The vast majority of the literature investigating intensive interventions consists of 3-5 sessions (45-60 minutes in duration) a week over 5-12 weeks. The only other treatment which promotes a dosage as

high as NAPA therapy is Constraint Induced Movement Therapy (CIMT) which has been shown to range between 1 to 24 hours a day, over a period of two weeks to two months, however, much of this is parent led/home practice. CIMT is a recommended treatment option as it has an immense amount of favourable high quality published literature and a good safety profile for those with a diagnosis of CP.[14, 15] In comparison, NAPA therapy utilises a "core combination" of the Neurosuit, SpiderCage and Cuevas Medek Exercise (CME). None of which are considered effective ('do it' or 'probably do it') interventions for CP. [14]

Suit therapy

The original suit (Adeli suit) was developed for the Soviet space program in the late 1960's and was referred to as the Penguin suit. It was designed to counteract the adverse effects of zero gravity including muscle atrophy and osteopenia, and maintain neuromuscular fitness during weightlessness. [16] In 1991, the Adeli suit incorporated a prototype of a device developed in Russia for children with CP and popularized by the EuroMed Rehabilitation Center in Mielno, Poland. [17] Since then, the suit has been popularised in different countries using different names (Therasuit, Neurosuit, PediaSuit etc.). [16, 18] These different suits are essentially the same thing, however, they are marketed according to their own 'protocols'. The differences between these 'protocols' are not clear in the literature, and most interventions use a combination of suits with intensive physical therapy (i.e. 2-4 hr sessions, 5-6 days a week, over 3 or 4 weeks). [18] Non-peer reviewed literature from developers of these suits claim that the therapy is appropriate for children from 2 years of age to adulthood. [18, 19]

In addition to the suit, some protocols use ability exercise units or functional cages. These cages can be used in two ways: the 'monkey cage' uses a system of pulleys and weights to isolate and strengthen specific muscles; and the 'spider cage' (Figure 1) uses a belt and bungee cords to either assist upright positioning or practice many other activities that normally would require the support of more therapists. [18] Claims of "significant improvement" following body weight suspension training have been made, however, only 3 peer reviewed articles exist. All of which are



methodologically weak and include small samples making it impossible to make conclusions about its effectiveness. [20-22]

Figure 1. Spider cage and universal therapy unit.

Some of the many reported benefits include improving motor function and posture, [23] improving vertical stability (e.g. standing posture), [24] increasing range of motion, [25] providing proprioceptive input and improving the vestibular system improving symmetry, [26] increasing walking speed and cadence, [27] improving trunk, [28] control motor function (in all dimensions of Gross Motor Function Measure [GMFM]), [29] and self-care [30] capacity in children with CP. However, most of these studies are case reports or descriptive studies in which the methodological quality limits the possibility of supporting or rejecting the use of the suit therapy in clinical settings.

Centres that offer suit therapy indicate that the therapy can help children diagnosed with: [31, 32]

- Cerebral Palsy
- Global Developmental Delays
- Traumatic Brain Injury
- Near Drowning Accidents
- Post stroke (CVA)
- Incomplete Spinal Cord Injury
- Ataxia
- Athetosis
- Spasticity
- Hypotonia
- Parkinson Disease
- Chromosomal Disorders
- Autism Spectrum Disorder

There are no published, peer-reviewed studies on any of the above listed diagnoses, except for CP.

Three moderate to high quality systematic reviews were analysed to obtain evidence on the benefit of participation in intensive suit therapy for children and adolescents with CP. These reviews are summarised in Table 2 below.

The main take-home messages from the analysis were:

- Evidence indicating greater functional benefit from participation in intensive suit therapy is limited.
- No studies investigated the feasibility (e.g. adherence/compliance) or cost-effectiveness of suit therapy
- It is not possible to draw conclusions regarding which children with CP may benefit more than others from suit therapies due to the limited evidence and heterogeneity of included participants (GMFCS level I-IV)
- There is no consensus with regard to frequency, intensity and timing due to the variability in doses delivered across studies. Often specific protocols (including other physical therapy interventions concurrently delivered) were not described in studies. This makes it extremely difficult to evaluate findings.

- Results from a meta-analysis showed a **small** positive effect size for gross motor function at post treatment (g=0.46, 95% confidence interval [CI] 0.10–0.82) and follow-up (g=0.47, 95% CI 0.03– 0.90). This small effect **does not** support robust conclusions to prescribe or suggest this new and 'promising' approach to therapy.
- Furthermore, adverse effects such as overheating, respiratory compromise, toileting problems such as constipation and urinary leakage and peripheral cyanosis have been reported. [16, 33]

Cuevas Medek Exercise

Cuevas Medek Exercise (CME) is a specialised psychomotor therapy designed for infants with developmental delays, syndromes and conditions affecting the central nervous system. [34] CME therapy provokes the child's automatic postural responses by exposing the infant to the influence of gravity through a variety of positions and exercises (approximately 3000 exercises exist). During CME, the therapist physically manipulates the child to stretch out tight muscles and train the muscles in groups. These manipulations eventually allow the child to gain control over his or her trunk, which is necessary to perform basic gross motor activities such as sitting, standing, and walking. Sessions begin on a table. Then, if the child is able to stand with ankle support, the floor is used. Floor exercises involve seven pieces of equipment, which can be configured in various ways to challenge the child's sense of balance. Exercises are repeated until the reaction of the brain becomes automatic and the body reacts normally to situations where required to keep its balance.

It should be noted that CME rejects the use of external supports (splints and walkers) and the exercises are manually applied by a therapist, rather than the patient having to physically make the movements themselves. Below is an excerpt from the thesis titled *The social construction of disability and the modern-day healer* by Vanderminden [35]which describes the process of CME as described by its creator, Ramon Cuevas.

"CME therapy can be exercised regardless of the emotional status of the child, while in classical approaches, if the child cries the therapy session is typically terminated. When considering a child's muscle tone, classic approaches generally will not place a child with hyper tonicity or severe spasticity in the standing position. Conversely, CME therapy practices the exact opposite. CME therapy does not require a physician's diagnosis of a child's condition, but rather seeks to listen to the parent's interpretation of the limitations of their child's development and movement."

CME is claimed to be suitable for babies from 4 months old, until they are walking and climbing stairs, however due to the nature of the technique, therapists are only able to work with children of a certain weight (up to approximately 22.5kg/50 pounds). [34] The therapy is suggested to occur three times a week, twice a day, for 45 minutes per session. [36]

Studies focused on CME are scarce. Apart from reports published by the creator of the technique, only two case reports published in very low ranked (Impact Factor <1.5) peer reviewed journals could be located. [36, 37] These studies report that technique leads to positive results, however, several factors need to be considered.

1) Treatment protocols were poorly reported

2) Unclear what outcome measures were used to determine “positive” results
3) No statistical analysis
4) Small samples/case reports
    a. Unclear how participants were selected and allocated to groups in the report with multiple participants [37]

Given the lack of scientific evidence or identification of possible adverse effects of this treatment it cannot be considered an evidence based practice. It should also be noted that CME is not listed as an intervention for CP in the high quality systematic review by Novak, Morgan [14] or the American OT association review into interventions to improve motor performance [38], furthermore, other authors have called for the treatment to be “discontinued based on current evidence.” [39]

Home based programs

Home programs have been used for years by families and therapists to increase the intensity of therapy, either between treatment sessions or during a break from therapy. Recent research into therapy intensity has concluded that home programs provide a pragmatic solution to achieving high dose therapy, thus overcoming existing systemic implementation barriers.[2, 40]

In relation to upper limb mobility, there is little evidence to support block therapy alone as the dose of intervention is unlikely to be sufficient to lead to sustained changes in outcomes. [40] There is strong evidence that goal-directed OT home programs are effective and could supplement hands-on direct therapy to achieve increased dose of intervention. [41] Embedding intervention in natural environments (e.g., home, preschool/school) has been suggested to lead to meaningful and generalizable improvements in function. [42]

Clinically proven high dose interventions such as bimanual training and constraint-induced movement therapy (CIMT) have been shown to be effective when delivered at home. [43-45] Home based interventions are beneficial, especially for interventions with dosages that are not feasible for most families.

Novak, Cusick [42] have developed five steps for delivering successful home based programs. This includes:

1) Establishing collaborative partnerships between therapist and caregivers
2) Having the child and family (not the therapist) set goals about what they would like to work on in the home environment
3) Establishing the home program by choosing evidence based interventions that match the child and family goals and empowering the parents to devise or exchange the activities to match the child’s preferences and the unique family routine
4) Providing regular support and coaching to the family to identify the child’s improvements and adjust the complexity of the program as needed; and
5) Evaluating the outcomes together

Based on the steps, therapy provided by NAPA would not be successful in a home based environment because:

a) The core interventions (suit therapy, spider cage and CME) are not evidence based
b) They cannot be performed in the home without the equipment utilised in the clinic
c) The NAPA centre is not local for many patients so provision of support and development of a collaborative partnership will be near impossible without regular interaction between therapists and patients/families
d) Outcomes won't be able to be evaluated unless further blocks of NAPA therapy are provided

Neuroplasticity and Gross Motor Function Classification Scores

Neuroplasticity is the brain's adaptive capacity to encode experiences as well as learn new behaviours and skills. In children with CP, intervention before the age of seven is recommended for optimizing motor function and learning functional skills, because from a maturational and neuroplasticity perspective the greatest gains will be made during this window. [46-48]

A younger child with a GMFCS level I or II usually has a better developmental prognosis than an older child with a GMFCS level IV or V. [49]

Gross motor development curves based on age and GMFCS level have been created by Rosenbaum, Walter [46] to enable prognosis of gross motor progress (Figure 2). Following this, Hanna, Bartlett [50] created reference curves which plotted percentiles at the 3rd, 5th, 10th, 25th, 50th, 75th, 90th, 95th, and 97th percentiles within each GMFCS level (Figure 3-7). This can be used to determine percentage potential based using GMFCS scores.

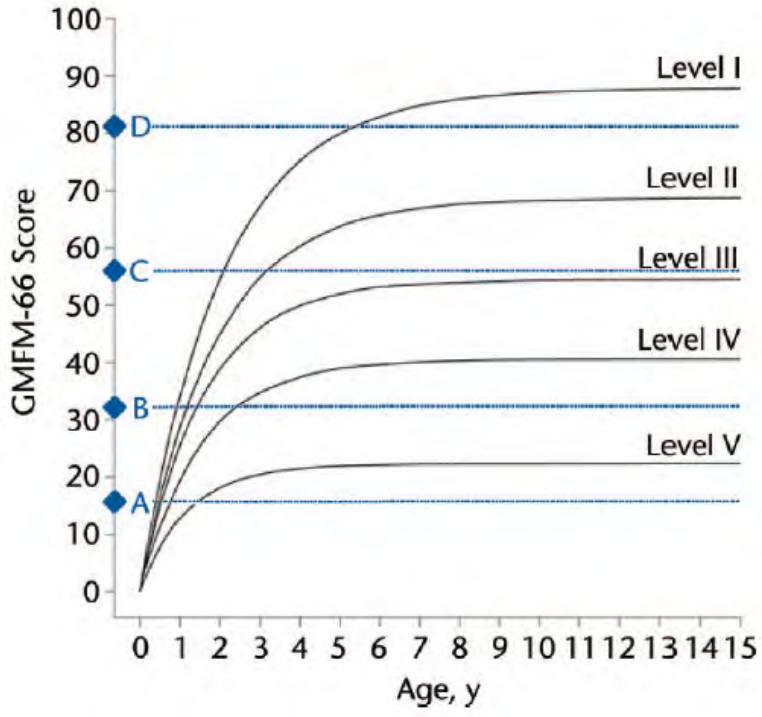


Figure 2. Gross motor development curves representing average development predicted by the Gross Motor Classification System. The diamonds on the vertical axis identify 4 items of the 66-item Gross Motor Function

Measure (GMFM-66) that predict when children are expected to have a 50% chance of completing that item successfully. The GMFM-66 item 21 (diamond A) assesses whether a child can lift and maintain his or her head in a vertical position with trunk support by a therapist while sitting, item 24 (diamond B) assesses whether a child can maintain a sitting position on a mat without support from his or her arms for 3 seconds, item 69 (diamond C) measures a child's ability to walk forward 10 steps without support, and item 87 (diamond D) assesses the task of walking down 4 steps by alternating feet with arms free.

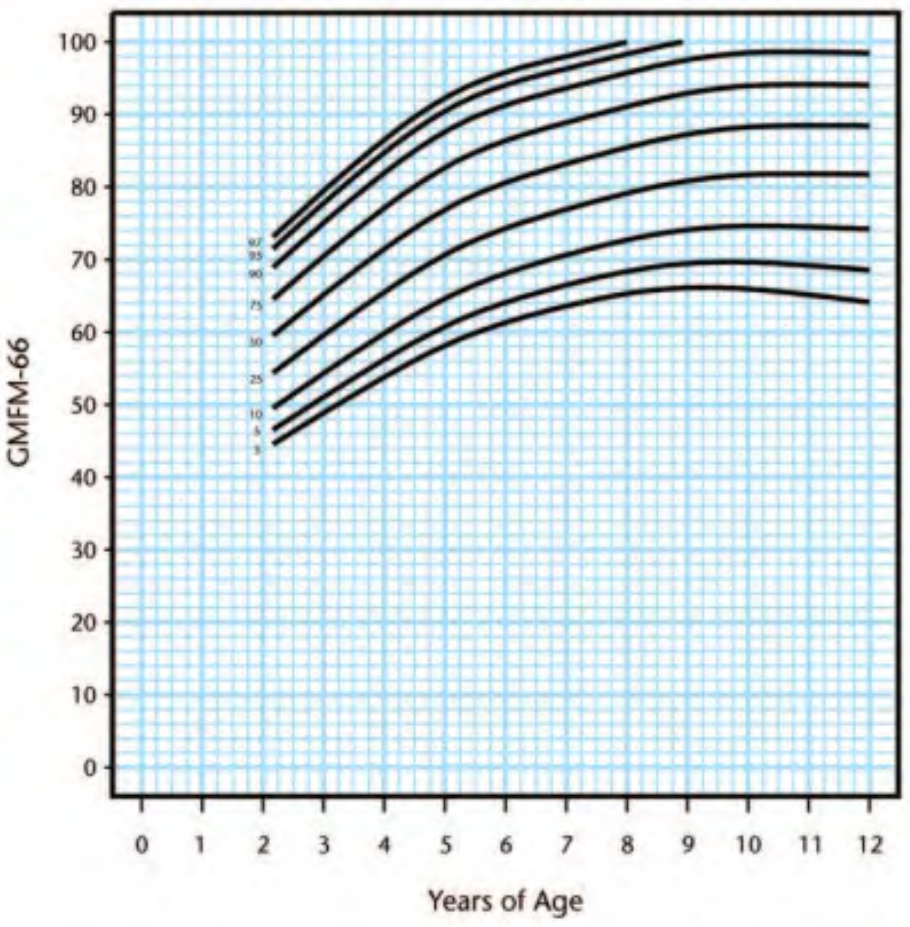


Figure 3. Gross Motor Function Classification System level I percentiles.

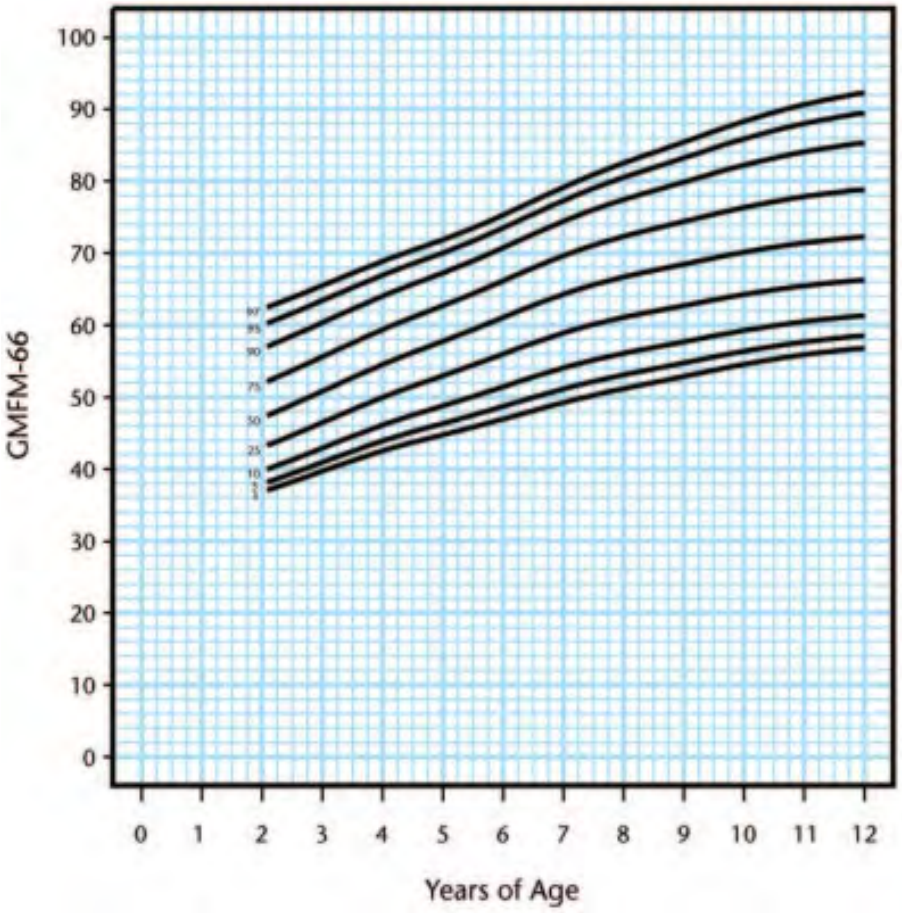


Figure 4. Gross Motor Function Classification System level II percentiles

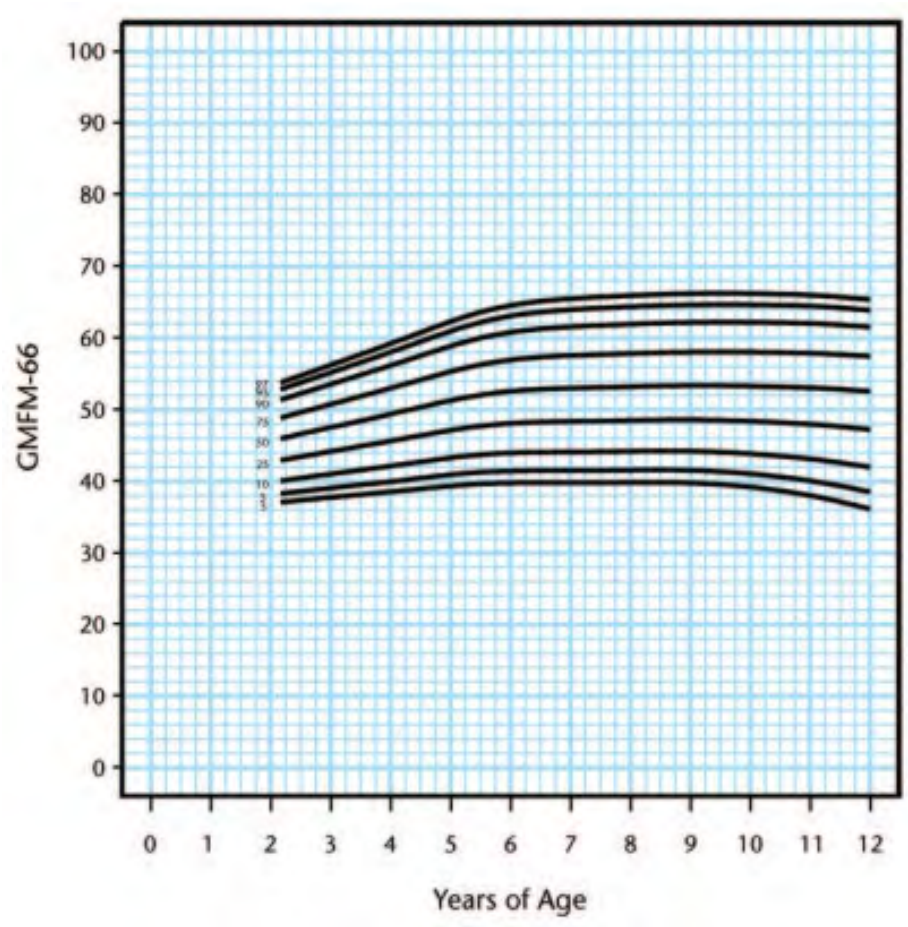


Figure 5. Gross Motor Function Classification System level III percentiles

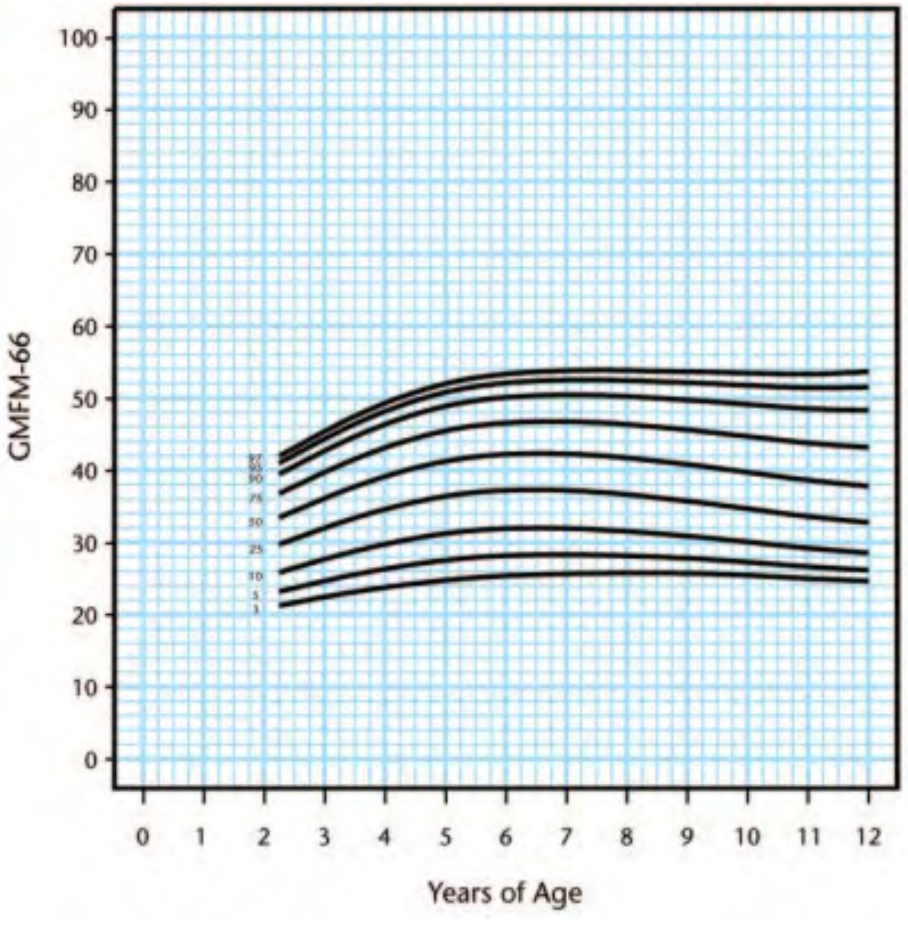


Figure 6. Gross Motor Function Classification System level IV percentiles

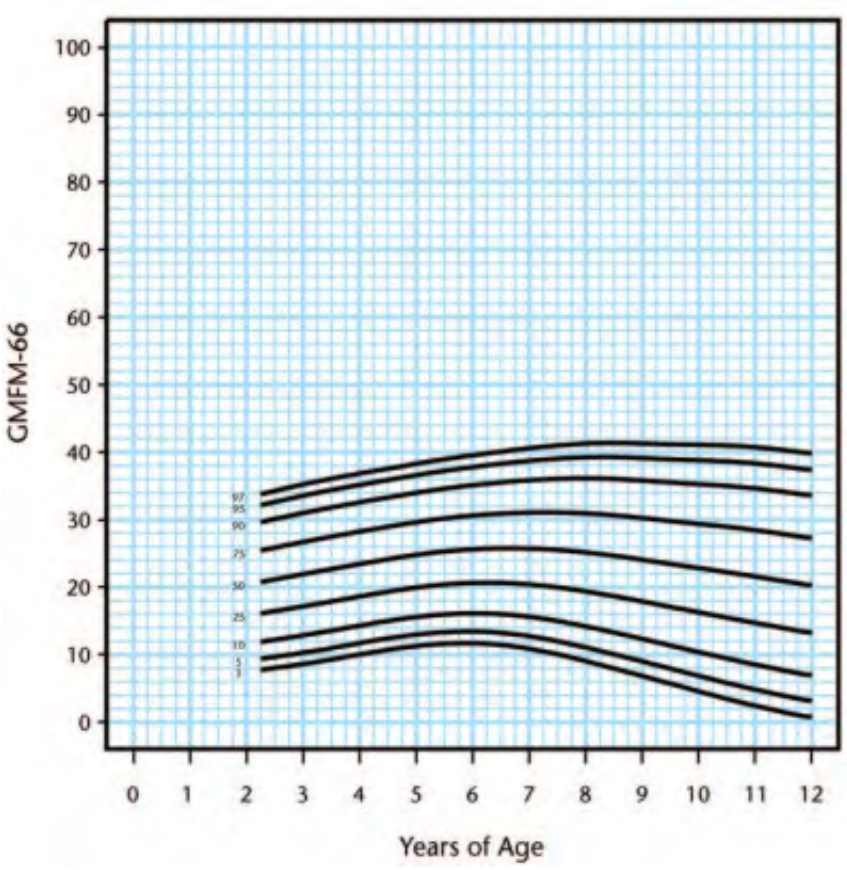


Figure 7. Gross Motor Function Classification System level V percentiles

Progressive disorders

Childhood neurodegenerative and neuromuscular disorders are rare, and usually have no cure. The natural history is often unknown and progression varies across patients.

Congenital neuromuscular disorders

Congenital neuromuscular disorders include:

- Muscular dystrophy
- Myotonic dystrophy
- Spinal muscular atrophy
- Peripheral neuropathies
- Generalised muscle and nerve issues (such as mitochondrial disorders)

The management of paediatric neuromuscular disorders is complex and challenging. Developing an effective management plan requires an understanding of the underlying pathophysiology, genetics, and natural history, as well as the interactions of normal maturation, treatment modalities, and the

environment. [51, 52] Optimum management requires a multidisciplinary approach that focuses on preventive measures as well as active interventions to address the primary and secondary aspects of the disorder. [51]

Physical therapy interventions

Active, active-assisted, and/or passive stretching to prevent or minimise contractures should be done a minimum of 4–6 days per week for any specific joint or muscle group. Stretching should be done at home and/ or school, as well as in the clinic. [51] **Nowhere in the literature is there mention of providing short-term intensive therapy (physio, OT or speech) blocks as part of the management plan for neuromuscular disorders.**

Figure X below provides a comprehensive overview of neuromuscular and skeletal management strategies for Duchenne muscular dystrophy. [51]

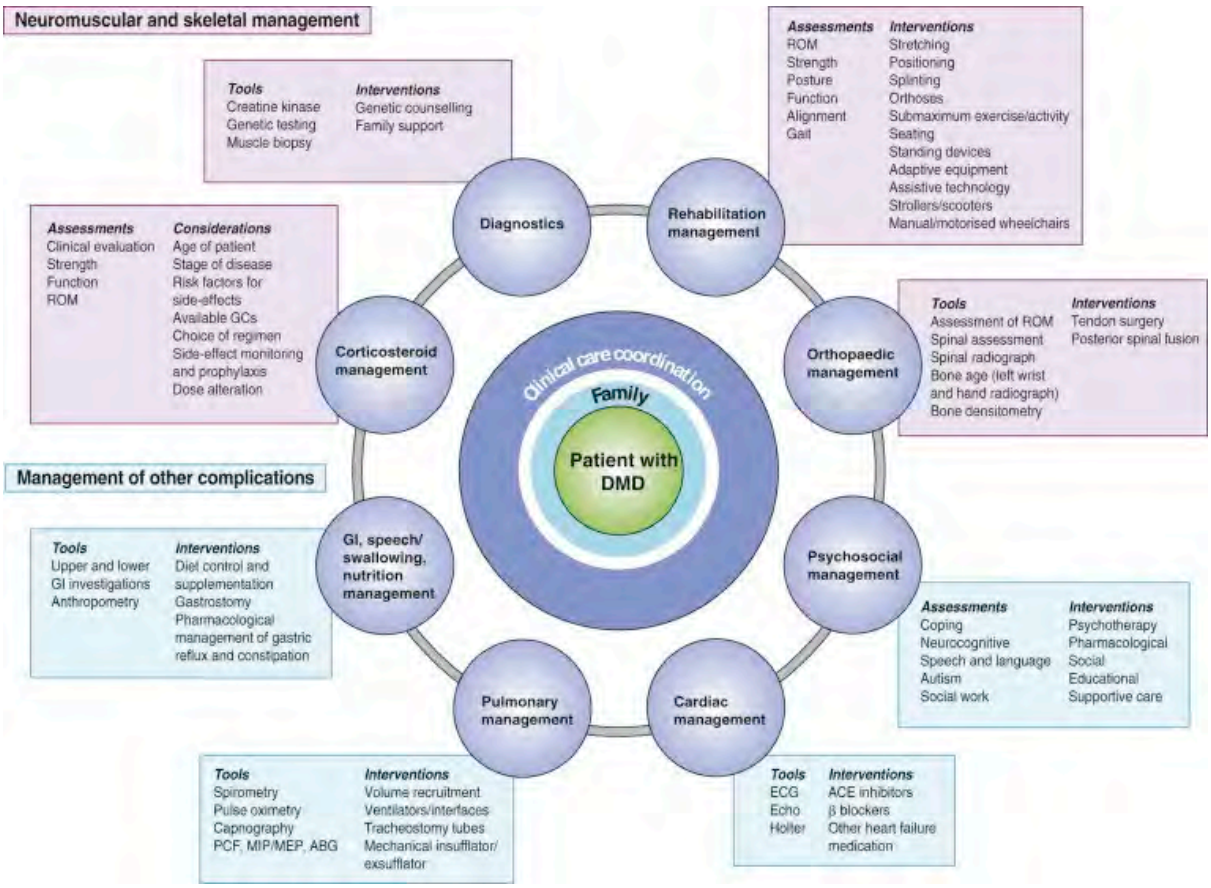


Figure X. neuromuscular and skeletal management strategies for Duchenne muscular dystrophy

Neurodegenerative Disorders in Childhood

Normal neural development and behaviour is relatively well understood, much less is known about the behavioural neurology of neurodegenerative deterioration in children. [53] It is unknown how the developing brain is impacted by progressive diseases at both a global and selective level. [53, 54] Frequently, the assessment of the severity of symptoms in children with neurodegenerative

disorders (NDD) is difficult. Age and understanding of the child are always a factor and, in addition, many children suffer from brain damage or intellectual disability as a result of their disease. [53]

Treatment of children with NDD is directed towards the underlying disorder, other associated features, and complications. [55] The treatable complications include; epilepsy, sleep disorder, behavioural symptoms, feeding difficulties, gastroesophageal reflux, spasticity, drooling, skeletal deformities, and recurrent chest infections. [55] These children require a multidisciplinary team approach with the involvement of several specialties including paediatrics, neurology, genetics, orthopaedics, physiotherapy, and occupational therapy. [55] Many newer antiepileptic drugs are now available to treat intractable epilepsy. [54] **owhere in the literature is there mention of providing short-term intensive therapy (physio, OT or speech) blocks as part of the management plan for NDD.**

An investigation by Olney, Doernberg [56] identifed 104 progressive brain disorders of childhood which may be mistaken for CP. The natural history of many of these conditions is unknown as insuffient numbers of cases are reported in the literature. [56]

Table 1: Literature investigating intensive therapy models

Author (year)	Study aim/objective	Methods/participant characteristics/outcome measures	Outcome/summary	Quality of included evidence +/- conclusion (High/Moderate/Low/Very Low)
Jackman, Lannin [6]	1. For children with cerebral palsy to achieve improvements in upper limb motor ability and individual goal achievement, are upper limb goal-directed, functional or non-functional interventions most effective? 2. Is there a minimum dose of upper limb practice that is likely to lead to improvements in motor ability and individual goals? 3. Can home practice supplement dose of therapy provided face to face with a therapist? 4. Is an "intensive" block of therapy (provided 3 times per week or greater) more effective than training provided at a lower intensity?	**Systematic Review** Inclusion criteria: (a) Randomised or quasi randomised controlled trial; (b) 100% of participants had a diagnosis of CP or brain injury (or high risk of CP in infants); (c) Mean age of participants was 0–18 years; and (d) The study investigated an active upper limb intervention. Extensive search terms were based on the following categories: (a) CP, (b) task-specific interventions, (c) upper limb, and (b) paediatric. Hand searches were carried out to identify additional references For a study to be classified as an upper limb task-specific intervention, the study had to involve (a) active movement of the upper limb, and (b) whole-task or part-task practice of tasks relevant to the child's age.	25 studies (707 participants; age range 18 months to 21 years) for motor function (Assisting Hand Assessment) and 20 studies (491 participants; age range 3 months to 17 years) for individual goal achievement (Canadian Occupational Performance Measure). Individual goals can be achieved with a dose of **14–25 hr of practice**, using a combination of face-to-face therapy with practice at home (5.6 hr of face to face and 8.4 hr of home practice) for children over 4 years of age. For younger children, it did appear that a higher dose of practice was indicated, although this was based on one study A threshold dose of between **30 (OR 3.25 [95% CI 0.9–12.2]) and 40 (OR 3.75 [95% CI 1.0–14.2])** of practice clinically significant improves motor ability in the unilateral CP population. The average ratio of therapy: home practice was 70:30. **Age–dose relationship suggested younger children (below the age of 8) are more likely to improve motor ability.** No significant difference between intensive (>3x per week) and less frequent. Intensity did not predict success or fail of set goals (OR 1.08 [95% CI 0.2–6.3]).	**High** Group mean data used instead of individual – may impact results Sample sizes small in some studies, however, high quality studies included. If the purpose of the intervention is to achieve individual goals, goal-directed interventions, in which goals are practiced, rather than focussing on underlying skills, are more effective.

	5. Is there an age–dose relationship?	**Outcome measures** AHA, Quality of Upper Extremity Skills Test (QUEST), Melbourne Assessment 2, The Box and Blocks Test, Abilhand-Kids, COPM, The Goal Attainment Scale (GAS), the Pediatric Evaluation of Disability Inventory (PEDI), and the Functional Independence Measure for children (WeeFIM). The AHA and COPM were the most commonly utilised reliable outcome measures within eligible studies	Practice at home appears to be an effective enhancement to face-to-face therapy. It is likely that if families are educated and supported to carry out practice at home, that this practice can be an effective and cost-effective enhancement in achieving goals. Practice within everyday environments may also facilitate transfer of skills beyond the clinic to the child's real life.	
Cope and Mohn-Johnsen [7]	(1) In children with cerebral palsy, is therapy provided for a greater total number of minutes more effective than the same intervention provided at fewer total minutes for improving motor function? (Time) (2) In children with cerebral palsy, is therapy provided at higher frequency (intermittent) more effective than the same intervention provided at a lower frequency (continuous) for improving motor function? (Frequency)	**Systematic Review & Meta-Analysis** inclusion criteria: Study design must include the same treatment across at least one of three dosage variables, specifically: (a) compare treatment time, defined for this review as any contrast in the total number of minutes; (b) compare treatment frequency, defined for this study as any contrast in scheduling of frequency (intermittent versus continuous) where total minutes of therapy remain constant; and (c) compare intensity in which the amount of effort by the study participant is varied by group;	9 RCTs and 1 retrospective non-randomized controlled trial (388 participants, age 4 months to 16 years) The functional level of the participants ranged from I to V on the GMFCS. The majority of participants throughout the studies included children with spastic cerebral palsy. The majority (8 of 10) of studies utilized either an eclectic (treatment not limited to one specific intervention) or neurodevelopmental treatment (NDT) approach The high-dosage therapy conditions ranged in frequency from one to seven times per week, with total therapy hours over the treatment duration ranging from 9 to 126 hours. Low-dosage therapy conditions ranged in frequency from one time per month to seven times per week, with total therapy	**Moderate** Methods of review were robust. Included studies highly variable. Not enough evidence exists to determine if higher frequency therapy is more effective than lower frequency. The findings from this review are limited to short-term effects only; follow-up data were sparsely reported.

	(3) In children with cerebral palsy, is intervention performed at a higher intensity more effective than the same intervention performed at a lower intensity for improving motor function? (Intensity)	intervention must be provided by a PT or OT intervention may focus on upper and/or lower limb; outcomes measures include impairments of body structure/ function, activity limitations, and/or participation restrictions; participants must be children, birth to 18 years with a diagnosis of cerebral palsy; publication in peer-reviewed journals in any language with English version available; controlled trials with two or more groups. **Data extracted** study design, sample size, subject demographics, intervention parameters, outcome measures, follow up procedures, baseline and post treatment group means and measures of variability, within-group change scores and measures of variability, and statistical significance for within group and between-group comparisons	hours over the treatment duration ranging from 6 to 78 hours. Results showed a **small treatment effect** favouring the higher dosage time (pooled g = 0.277, 95% CI 0.02, 0.534; I2 = 0%), however, this benefit is **not clinically important.** All individual between group differences showed wide confidence intervals that crossed zero, suggesting both lack of precision in the computed effect sizes and the possibility that there was no difference between the groups.	
Myrhaug, Østensjø [2]	To describe and categorise intensive motor function and functional skills training among young children with CP, and to summarise the effects of these interventions.	**Systematic review & Meta-Analysis** Inclusion criteria: (a) a study population of CP with a mean age <7 years; (b) evaluated the effects of motor function (e.g., mobility and grasping) and functional skills training (e.g., eating and playing) performed three times or more per	38 studies included 1407 children with all levels of gross and fine motor function Only 6/38 studies performed intervention more than 1 hr a day. More common for 2-7 sessions a week + home training (19/38) and these were mainly hand function interventions. In a majority of the studies, equal improvements in motor function and functional skills were identified	**Moderate** Small studies, often without power calculations, were also included. A variety of interventions were used to improve gross motor function and functional skills, which prevented the

		week at the clinic, in the kindergarten, or at home; (c) was compared to another intervention (e.g., conventional therapy), the same type of intervention provided less frequently, or another intensive intervention; and (d) with outcomes in the activity and participation components of the ICF [3], measured as hand function, gross motor function, and/or functional skills. In addition, the included studies were required to be controlled trials, published in peer review journals <u>Data extracted</u> study population, design, interventions, comparison, outcome measures, and results The intensity of training was described as the amount of training and duration of the training periods. The amount was categorised into four groups according to frequency of sessions and use of home training: (1) 2–7 training sessions per week with additional home training, (2) 3–7 training sessions per week, (3) training more than one hour per day, and (4) training more than one	for intensive interventions and conventional therapy or between two different intensive interventions **Hand function (fine motor skills)** When compared with conventional therapy, CIMT performed for more than one hour per day showed significant effects on unilateral hand function in one meta-analysis (N = 2, [33,60] SMD 0.79 (95% CI 0.03, 1.55), p = 0.04). The CIMT groups performed 15–28 hours more training per week, which resulted in a difference of 29–84 training hours over two to three weeks compared with the conventional therapy groups. **Gross motor function** Too heterogeneous to be pooled in meta-analyses. All studies with significant results in favour of intensive training that targeted gross motor function had a high risk of bias. **Functional skills** CIMT performed at least 2–7 sessions per week with additional home training achieved more improvements in functional skills compared with conventional therapy (N = 3, [36,38,60] SMD 0.82 (95% CI 0.26, 1.38), p = 0.004) and (2) CIMT performed 2–7 sessions per week with additional home training achieved more improvements in functional skills compared with intensive bimanual home training (N = 4, [21,30,32,34] SMD 0.50 (95% CI 0.16, 0.83), p = 0.004)	pooling of results in the meta-analyses. **19/38 studies had high risk of bias. Therefore, results remain uncertain.** The identification of the optimal intensity of interventions that target motor function and functional skills, as well as the possible harmful effects of intensive training, requires further investigation.

		hour per day with additional home training. The duration was categorised as ≤ four weeks, 5–12 weeks, or >12 weeks.		
Arpino, Vescio [5]	To assess whether intensive 'conventional therapy' is more effective than non-intensive 'conventional therapy' in children with CP whose clinical outcome was assessed with the GMFM.	**Systematic review & Meta-analysis** Type of study: RCT Type of participants: infant/children/adolescents (1–18 years old) affected by any type of CP. Outcome measure: GMFM. 'intensive' treatment was defined as any treatment provided more than 3 times per week; in a single study, additional sessions provided by an assistant defined the 'intensity' of the treatment. 'Conventional therapy' that which included physiotherapy or a neurodevelopmental approach.	Meta-analysis showed that the GMFM change score was higher for the intensive treatment group, compared with the non-intensive treatment group **[difference of 1.32; 95% confidence interval (CI): 0.55–2.10].** Effect of intensive treatment tended to be stronger for children who were 2 years of age or younger (difference of 5; 95% CI: – 0.45–10.45). In the RCTs in which treatment lasted for at least 60 days, it was higher in the intensive treatment group than in the non-intensive treatment group (difference of **1.42**; 95% CI: 0.55–2.30).	**High** **According to the GMFM-88 manual an increase of 1.82% points is the smallest change of clinical importance according to parents' perception** Limited evidence to support intensive/additional physiotherapy
Elgawish and Zakaria [41]	To assess gross motor progress in children with spastic (quadriplegic and diplegic) CP treated with intensive physical therapy (PT) as compared with a matched group treated with a standard PT regimen.	**Randomised controlled trial** Patients were randomly assigned to two treatment groups: group A and group B Convenience sample. Intensive PT = 5 sessions (1hr each) a week, over 16 weeks	After 8 weeks, there were significant differences between the two groups as regards the total scores of GMFM-88 and GMPM ($P < 0.05$). However, highly significant differences for GMFM-88 ($P < 0.001$) and only significant differences ($P < 0.05$) for GMPM were observed after 16 weeks.	**Moderate** Convenience sample. Randomisation not specified, no power calculation. Intensive PT led to greater motor function

		Standard PT =2 sessions (1hr each), over 16 weeks 25 girls and 20 boys, aged between 2 and 6 Years GMFCS level I - V	No statistically significant differences were found between the two groups as regards GMFM-66 scores after 8 weeks, and significant differences were found only after 16 weeks ($P < 0.05$). **After 16 weeks, all dimensions of GMFM-88 were significantly increased in both groups ($P < 0.001$).**	improvements. However, even 1hr, twice a week leads to significant improvements.
Christiansen and Lange [57]	to compare the effect of the delivery of the same amount of intermittent versus continuous physiotherapy given to children with cerebral palsy (	**Randomised controlled trial** 25 children up to 10 years of age (16 males, nine females; median age 3y 2mo, range 1y 2mo–8y 9mo) Convenience sample. GMFCS level I – V <u>Intermittent =</u> physiotherapy 4x a week, 45 minutes per session for 4 weeks (period A) followed by 6 weeks without physiotherapy (period B). Periods A and B were repeated three times over 30 weeks with a maximum of 48 sessions <u>Continuous =</u> physiotherapy once or twice a week for 30 weeks, also for 45 minutes per session and with a maximum of 48 sessions Children were treated by 'their own' physiotherapist during the intervention <u>Outcome measure</u>	Both groups increased their GMFM scores significantly over the study period (I group p=0.026; C group p=0.038). Result does not confirm the hypothesis that intermittent physiotherapy increases the GMFM-66 score more than continuous physiotherapy	**Moderate** Convenience sample. Randomisation not specified. More studies required.

		GMFM-66		
Bower, Michell [58]	to determine whether motor function and performance is better enhanced by intensive physiotherapy or collaborative goal-setting in children with cerebral palsy	**Randomised controlled trial** A convenience sample of 56 children with bilateral CP classified at level III or below on the Gross Motor Function Classification System (GMFCS), aged between 3 and 12 years. 4 treatment regimens provided by their own physiotherapist during the treatment period: (1) current pattern of physiotherapy to continue for each child; (2) current pattern of physiotherapy to be provided more intensively, one hour per day Monday to Friday; (3) therapy to be guided by collaborative setting of specific, individual, and measurable goals at the current intensity, i.e. amount as in Group 1; (4) therapy to be guided by collaborative setting of specific, individual, and measurable goals and provided more intensively, one hour per day Monday to Friday <u>Outcome measure</u> GMFM-88	There was no statistically significant difference in the scores achieved between intensive and routine amounts of therapy or between aim-directed and goal-directed therapy in either function or performance. Intensive physiotherapy, in contrast to collaborative goal-setting, produced a trend towards improvement in the GMFM scores which was not statistically significant. This trend declined in the follow-up observation period.	**Moderate** Randomised, power calculation and good CI estimates. The results of this trial suggest that for children aged 3 to 12 years with bilateral CP at levels III or below on the GMFCS, altering their routine physiotherapy by increasing its intensity for a period of six months has very little effect upon the outcome of gross motor function or performance at the end of this time.

Table 2. Summary of systematic reviews investigating intensive suit therapy as a treatment for CP

Author (year)	Study aim/objective	Methods/participant characteristics/outcome measures	Outcome/summary	Quality of included evidence +/- conclusion (High/Moderate/Low/Very Low)
Almeida, Fonseca [59]	To evaluate the available evidence on the effects of interventions based on the use of therapeutic suits in the treatment of impairments and functional limitations of children with cerebral palsy.	**Systematic Review** Inclusion: children and adolescents with CP, no restriction on study design or year of publication Exclusion: procedures of the intervention not described, no reporting of inferential statistics Data extracted • author and year of publication • study design • sample size and characteristics • details of the intervention: frequency, duration, suit type and settings • activities performed and control intervention • outcomes analysed using inferential statistics and the instrumentation used • results obtained GRADE guidelines used to grade the strength of the recommendation of the intervention	13 studies met inclusion criteria 285 children with different clinical types of CP aged 3-17 years with Gross Motor Function Classification System (GMFCS) level 1 to IV 6 RCT, 5 quasi-experimental designs, 2 single-subject experimental designs. Interventions with the suits ranged from three to 18 weeks, with usage times ranging between 30 min and 12 h/day. Different standardized instruments evaluated outcomes focusing on: • Body structures and functions • Activity Full Body Suit (FBS) n = 2 • Suit worn for 6 hrs a day for 6 weeks • Conflicting results found between studies for mobility scores Dynamic Elastomeric Fabric Orthose (DEFO) (neoprene pants that exert pressure on the pelvis and promote hip external rotation and abduction and knee extension) n = 2 • Suit worn for 4-8 hrs a day over 6 weeks • Not all participants increased walking speed • Some improvements in knee alignment	**Moderate** Low to very low quality of evidence. Weak recommendations for all interventions, a strong negative recommendation for the use of the FBS. Selected studies did not have sufficient information about (1) Direction and level of tension applied to the elastic elements in order to adjust the suits and (2) Exercises and activities conducted during the therapy sessions. (3) sufficient and appropriate intensity and duration of suit wearing to enable effects (4) which children with CP might be better candidates for obtaining the effect

			• Wearing this suit did not lead to significant difference in postural control <u>TheraTogs n = 3</u> • Suit worn 12 hrs a day for 12 weeks • Significant improvement seen in gait kinematics across all studies compared to control groups <u>TheraSuit Method (TSM) or AdeliSuit Therapy (AST) n = 6</u> • Both Therasuit studies found minimal gain (small positive effect sizes). • No statistically significant differences between groups [23, 27] • Some areas there was a decline in gross motor function [27] • Those with higher level motor function at baseline performed better [23] • <u>Only care giver perception regarding the performance of tasks obtained a large effect size</u> • Same findings relating to Adeli suit therapy	
Karadağ-Saygı and Giray [33]	To evaluate the clinical aspects and effectiveness of suit therapy for patients with cerebral palsy	**Systematic Review** <u>Inclusion</u> • <u>Patients</u>: Children (<18 years) with a diagnosis of CP • <u>Intervention</u>: Suit therapies • <u>Comparison</u>: Conventional therapy, neurodevelopmental therapy, or another therapeutic approach	29 studies were included of which 10 (34.5%) were Class I, eight were (27.6%) Class II-III, and 11 (37.9%) were Class IV **Types of participants** • Age ranged between 3 and 14 years. • Sample size ranged from 16 to 51. • Fourteen (48.28%) of the studies did not report the GMFCS level of the participants. **Intervention protocols**	**Moderate** Heterogeneity of studies makes it difficult to provide any guidance for clinical practice. Small sample sizes of included studies and varying protocols

		• Outcome: The clinical aspects of studies (number of participants, age, CP type, Gross Motor Function Classification System (GMFCS) level, suit type, intervention including dose of suit therapy, outcome measurements, outcomes, adverse effects, and funding) • Study: All types of trials published in peer reviewed journals including RCTs and non-RCTs and other studies (single case studies or case series) Data extracted • Number of participants • Age • CP type, • GMFCS level • Suit type • Intervention including dose of suit therapy • Outcome measurements • Adverse effects	• Intervention protocols varied within and between studies • Suit designs also differed among studies and varied among study participants in some of the studies • Nine (31.03%) of the studies investigated the effect of suit on upper limb function, while 10 of them investigated effects on lower limb function (e.g. gait analysis parameters, balance or walking performance tests) **Types of outcome measures** • The Gross Motor Function Measure was the most reported outcome • Participation evaluated using the International Classification of Functioning, Disability, and Health were limited • Seventeen (58.62%) of the studies did not report parental satisfaction or adverse effects. **Results synthesis** • A single RCT of high quality showed that full body suit therapy in additional to conventional therapy is beneficial in improving gross motor function in diplegic CP • Moderate quality evidence from 4 RCTs showed that suit therapy in addition to conventional therapy yields no significant change in GMFM compared to conventional therapy in children with diplegic and tetraplegic CP. • None of the studies investigated the feasibility (e.g adherence/compliance), and cost-effectiveness.	Included low quality studies (case studies etc) Further studies including large numbers of children with CP at different functional levels and ages are required in order to establish impact in children with CP at different functional levels and ages via subgroup analysis

			• Adverse effects were reported in 11 of the included studies. The reported undesirable effects were difficulty in donning/doffing, toileting problems such as constipation and urinary leakage, decrease in respiratory function, heat and skin discomfort (e.g. hyperthermia in summer, cyanosis)	
Martins, Cordovil [16]	An overview of the efficacy of suit therapy on functioning in children and adolescents with cerebral palsy.	**Systematic Review & Meta-Analysis** <u>Inclusion criteria</u> • RCTs reported in peer-review journals • Languages: English, Portuguese, Spanish and French • Studies investigating the effect of suit therapy regardless of the type of protocol used (Pedia- Suit, TheraSuit, NeuroSuit, Adeli suit, Penguin suit, or Bungy suit); • Studies conducted with samples that comprised children and adolescents (from 0–18y) with a clinical diagnosis of CP regardless of the type and level of severity • Studies reporting functioning as the primary outcome, assessed by means of standardized and internationally accepted instruments (e.g. GMFM – 66 or 88 items and Paediatric Evaluation of Disability Inventory [PEDI]). <u>Data extracted</u> • Type of study design • Sample size	Four studies were eligible and included in the review 110 participants included Mean number of participants in each trial was 12.3 (SD 2.52) with a mean age of 6 years 11 months (SD 1y 10mo). • Two RCTs compared Adeli suit treatment with neurodevelopmental treatment (NDT) • one study compared modified suit therapy with conventional therapy • One compared TheraSuit with a treatment categorized as 'other' <u>Sample</u> • CP severity ranged from I to IV • Subtypes included spastic, ataxic and dyskinetic • Topographic distribution of motor signs – hemiplegia, diplegia and quadriplegia • Total hours of treatment ranged from 30-60 Adeli suit showed significant improvements in gross motor function after 1 month of treatment (p=0.037). However, there was a decrease in gross motor function at follow up (9 months) and not	**High** Overall, studies were rated as 'fair' to 'good' quality using the PEDRO scale. The results of the study point to limited effects of suit therapy in gross motor function of children and adolescents with CP, and considerable levels of heterogeneity between trials. The presence of potential co-interventions (such as additional interventions and home training of parents with their children) remained unclear in most studies and might have influenced outcomes. There is no consensus about the adequate duration of suit therapy programs.

		• Instruments • Intervention protocol • Outcomes <u>Methodological quality</u> PEDro scale	difference between Adeli suit and NDT when the retention of motor skills was tested. This suggests that AST could result in short-term gains quickly, although long-term improvements in gross motor function may occur best with traditional NDT methods. Remaining RCT's showed variable results: • 2 showed significant differences between suit therapy and conventional/control groups • 1 showed no difference between TheraSuit and control suit when delivered as part of an intensive therapy program No studies fully specify the type of activities and exercises performed by participants in the experimental conditions who enrolled in different protocols of suit therapy, and those in the control conditions. **Meta-Analysis** **<u>Small</u>**, pooled effect sizes were found for gross motor function at post treatment (<u>g=0.46,</u> 95% confidence interval [CI] 0.10–0.82) and follow-up (**<u>g=0.47</u>**, 95% CI 0.03– 0.90).	Health professionals should take into consideration the lack of scientific evidence regarding the effectiveness of suit therapy when advising parents who are enquiring about this costly and time-consuming treatment option. In summary, the results of this systematic review and meta-analysis do not support robust conclusions to prescribe or suggest this new and 'promising' approach to therapy.
Wells, Marquez [1]	To conduct a systematic review asking, does garment therapy improve motor function in children with cerebral palsy?	**Systematic Review & Meta-Analysis** Electronic searches of EMBASE, MEDLINE, Cochrane Library, PubMed, CINAHL and Proquest Inclusion criteria: Children <18 years, any sub classification of CP, intervention involved suit/garment therapy and included a measure of neuromuscular function	14 studies included in the review (n = 234) Age 15 months to 17 years (mean = 8.1 years). Primary reported impairment was spasticity (74.76%). 5 RCT, 9 were case studies (single case study, repeated measures or case report). 4 studies full body suits, 6 studies full body suits in conjunction with a strapping system, 2 upper limb	**Moderate** Limited number and varying quality of studies Whilst there is some evidence for the use of garment therapy it is not sufficiently robust to recommend the prescription of garment

			garment, 1 study lower limb garment, 1 full body suit including gloves. Garment brands were Second Skin, the Adeli Suit, TheraTogs, TheraSuit, UpSuit, and Camp Lycra 9 described adverse events that may have been a consequence of the intervention Intervention duration = 3-12 weeks Garment wear time = 2-12 hours per day <u>Meta-Analysis</u> Non-significant effect on post-intervention function as measured by the Gross Motor Function Measure when compared to controls (MD = −1.9; 95% CI = −6.84, 3.05). Non-significant improvements in function were seen long-term (MD = −3.13; 95% CI = −7.57, 1.31). Garment therapy showed a significant improvement in proximal kinematics (MD = −5.02; 95% CI = −7.28, −2.76), however significant improvements were not demonstrated in distal kinematics (MD = −0.79; 95% CI = −3.08, 1.49).	therapy instead of, or as an adjunct to conventional therapy options.

Revision History

Revision	Revised by	Cleared by	Date	Research Register No.	HPE No.	Summary of Revision
Literature search and review	Jane Scheetz	N/A	05/03/21	2020/0135	NED20/466233	Systematic review and meta-analysis by Wells et al added to literature review table

Reference List

1. Wells H, Marquez J, Wakely L. Garment Therapy does not Improve Function in Children with Cerebral Palsy: A Systematic Review. Physical & Occupational Therapy In Pediatrics [Internet]. 2018 2018/08/08; 38(4):[395-416 pp.]. Available from: https://doi.org/10.1080/01942638.2017.1365323.

2. Myrhaug H, Østensjø S, Larun L, Odgaard-Jensen J, Jahnsen R. Intensive training of motor function and functional skills among young children with cerebral palsy: a systematic review and meta-analysis. BMC Pediatrics [Internet]. 2014 2014/12/05; 14(1):[292 p.]. Available from: https://doi.org/10.1186/s12887-014-0292-5.

3. Eliasson AC, Krumlinde-Sundholm L, Gordon AM, Feys H, Klingels K, Aarts PBM, et al. Guidelines for future research in constraint-induced movement therapy for children with unilateral cerebral palsy: an expert consensus. Developmental Medicine & Child Neurology [Internet]. 2014; 56(2):[125-37 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/dmcn.12273.

4. Palisano RJ, Begnoche DM, Chiarello LA, Bartlett DJ, McCoy SW, Chang H-J. Amount and Focus of Physical Therapy and Occupational Therapy for Young Children with Cerebral Palsy. Physical & Occupational Therapy In Pediatrics [Internet]. 2012 2012/10/15; 32(4):[368-82 pp.]. Available from: https://doi.org/10.3109/01942638.2012.715620.

5. Arpino C, Vescio MF, De Luca A, Curatolo P. Efficacy of intensive versus nonintensive physiotherapy in children with cerebral palsy: a meta-analysis. International Journal of Rehabilitation Research [Internet]. 2010; 33(2):[165-71 pp.]. Available from: https://journals.lww.com/intjrehabilres/Fulltext/2010/06000/Efficacy_of_intensive_versus_nonintensive.10.aspx.

6. Jackman M, Lannin N, Galea C, Sakzewski L, Miller L, Novak I. What is the threshold dose of upper limb training for children with cerebral palsy to improve function? A systematic review. Australian Occupational Therapy Journal [Internet]. 2020; 67(3):[269-80 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/1440-1630.12666.

7. Cope S, Mohn-Johnsen S. The effects of dosage time and frequency on motor outcomes in children with cerebral palsy: A systematic review. Developmental Neurorehabilitation [Internet]. 2017 2017/08/18; 20(6):[376-87 pp.]. Available from: https://doi.org/10.1080/17518423.2017.1282053.

8. Russell DJ, Rosenbaum P, Wright M, Avery LM. Gross Motor Function Measure (GMFM-66 & GMFM-88) users manual. United Kingdom: Mac Keith Press; 2002.

9. Damiano DL, Abel MF. Functional outcomes of strength training in spastic cerebral palsy. Archives of Physical Medicine and Rehabilitation [Internet]. 1998 1998/02/01/; 79(2):[119-25 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S0003999398902878.

10. Damiano DL, Vaughan CL, Abel ME. Muscle Response to Heavy Resistance Exercise in Children with Spastic Cerebral Palsy. Developmental Medicine & Child Neurology [Internet]. 1995; 37(8):[731-9 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1469-8749.1995.tb15019.x.

11. Dodd KJ, Taylor NF, Graham HK. A randomized clinical trial of strength training in young people with cerebral palsy. Developmental Medicine & Child Neurology [Internet]. 2003; 45(10):[652-7 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1469-8749.2003.tb00866.x.

12. Eagleton M, Iams A, McDowell J, Morrison R, Evans CL. The Effects of Strength Training on Gait in Adolescents with Cerebral Palsy. Pediatric Physical Therapy [Internet]. 2004; 16(1). Available from: https://journals.lww.com/pedpt/Fulltext/2004/01610/The_Effects_of_Strength_Training_on_Gait_in.5.aspx.

13. Engsberg JR, Ross SA, Collins DR. Increasing Ankle Strength to Improve Gait and Function in Children with Cerebral Palsy: A Pilot Study. Pediatric Physical Therapy [Internet]. 2006; 18(4):[266-75 pp.]. Available from: https://journals.lww.com/pedpt/Fulltext/2006/01840/Increasing_Ankle_Strength_to_Improve_Gait_and.6.aspx.

14. Novak I, Morgan C, Fahey M, Finch-Edmondson M, Galea C, Hines A, et al. State of the Evidence Traffic Lights 2019: Systematic Review of Interventions for Preventing and Treating Children with Cerebral Palsy. Current Neurology and Neuroscience Reports [Internet]. 2020 2020/02/21; 20(2):[3 p.]. Available from: https://doi.org/10.1007/s11910-020-1022-z.

15. Hoare BJ, Wallen MA, Thorley MN, Jackman ML, Carey LM, Imms C. Constraint-induced movement therapy in children with unilateral cerebral palsy. Cochrane Database of Systematic Reviews [Internet]. 2019; (4). Available from: https://doi.org//10.1002/14651858.CD004149.pub3.

16. Martins E, Cordovil R, Oliveira R, Letras S, Lourenço S, Pereira I, et al. Efficacy of suit therapy on functioning in children and adolescents with cerebral palsy: a systematic review and meta-analysis. Developmental Medicine & Child Neurology [Internet]. 2016; 58(4):[348-60 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/dmcn.12988.

17. Turner AE. The efficacy of Adeli suit treatment in children with cerebral palsy. Developmental Medicine & Child Neurology [Internet]. 2006; 48(5):[324- pp.]. Available from: https://www.cambridge.org/core/article/efficacy-of-adeli-suit-treatment-in-children-with-cerebral-palsy/75AFA67F81E658CD64D18773CC5E438E.

18. Scheeren EM, Mascarenhas LPG, Chiarello CR, Costin ACMS, Oliveira L, Neves EB. Description of the Pediasuit ProtocolTM. Fisioterapia em Movimento [Internet]. 2012; 25:[473-80 pp.]. Available from: http://www.scielo.br/scielo.php?script=sci_arttext&pid=S0103-51502012000300002&nrm=iso.

19. Koscielny R. Strength training and CP. Available from: http://www.suittherapy.com/download%20center/artilces/Strenght%20Training%20and%20CP.pdf.

20. Liaqat S, Butt MS, Javaid HMW. Effects of Universal Exercise Unit Therapy on Sitting Balance in Children with Spastic and Athetoid Cerebral Palsy: A Quasi-Experimental Study. Khyber Medical

University Journal [Internet]. 2016; 8(4):[177- pp.]. Available from: http://www.kmuj.kmu.edu.pk/article/view/16786.

21. Emara HA, El-Gohary TM, Al-Johany AA. Effect of body-weight suspension training versus treadmill training on gross motor abilities of children with spastic diplegic cerebral palsy. Eur J Phys Rehabil Med [Internet]. 2016 Jun; 52(3):[356-63 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/26845668/.

22. Menz SM, Hatten K, Grant-Beuttler M. Strength Training for a Child With Suspected Developmental Coordination Disorder. Pediatric Physical Therapy [Internet]. 2013; 25(2). Available from: https://journals.lww.com/pedpt/Fulltext/2013/25020/Strength_Training_for_a_Child_With_Suspected.18.aspx.

23. Bar-Haim S, Harries N, Belokopytov M, Frank A, Copeliovitch L, Kaplanski J, et al. Comparison of efficacy of Adeli suit and neurodevelopmental treatments in children with cerebral palsy. Developmental Medicine & Child Neurology [Internet]. 2006; 48(5):[325-30 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1017/S0012162206000727.

24. Nemkova SA, Kobrin VI, Sologubov EG, Iavorskiĭ AB, Sinel'nikova AN. [Regulation of vertical posture in patients with children's cerebral paralysis treated with the method of proprioceptive correction]. Aviakosm Ekolog Med [Internet]. 2000 2000; 34(6):[40-6 pp.]. Available from: http://europepmc.org/abstract/MED/11253723.

25. Gracies J-M, Marosszeky JE, Renton R, Sandanam J, Gandevia SC, Burke D. Short-term effects of dynamic Lycra splints on upper limb in hemiplegic patients. Archives of Physical Medicine and Rehabilitation [Internet]. 2000 2000/12/01/; 81(12):[1547-55 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S0003999300546231.

26. Morris C, Bowers R, Ross K, Stevens P, Phillips D. Orthotic management of cerebral palsy: recommendations from a consensus conference. NeuroRehabilitation [Internet]. 2011; 28(1):[37-46 pp.]. Available from: https://strathprints.strath.ac.uk/40443/1/fulltext.pdf.

27. Bailes AF, Greve K, Schmitt LC. Changes in Two Children with Cerebral Palsy After Intensive Suit Therapy: A Case Report. Pediatric Physical Therapy [Internet]. 2010; 22(1). Available from: https://journals.lww.com/pedpt/Fulltext/2010/02210/Changes_in_Two_Children_with_Cerebral_Palsy_After.11.aspx.

28. Neves EB, Krueger E, de Pol S, de Oliveira MCN, Szinke AF, de Oliveira Rosário M. Benefits of intensive neuromotor therapy (TNMI) for the control of the trunk of children with cerebral palsy. Neuroscience Magazine [Internet]. 2013; 21(4):[549-55 pp.]. Available from: https://periodicos.unifesp.br/index.php/neurociencias/article/download/8141/5673.

29. Datorre E. Intensive Therapy Combined with Strengthening Exercises Using the Thera Suit in a child with CP: A Case Report. American Association of Intensive Pediatric Physical Therapy [Internet]. 2005. Available from: http://www.suittherapy.com/pdf%20research/Int.%20Therapy%20%20Research%20Datore.pdf.

30. Semenova KA. Basis for a method of dynamic proprioceptive correction in the restorative treatment of patients with residual-stage infantile cerebral palsy. Neuroscience and Behavioral Physiology [Internet]. 1997 1997/11/01; 27(6):[639-43 pp.]. Available from: https://doi.org/10.1007/BF02461920.

31. NAPA Centre. NeuroSuit 2020 [Available from: https://napacentre.com.au/our-programs/neurosuit/.

32. Ability Plus Therapy. Intensive suit therapy 2014 [Available from: http://abilityplustherapy.com/got-therapy/intensive-suit-therapy/.

33. Karadağ-Saygı E, Giray E. The clinical aspects and effectiveness of suit therapies for cerebral palsy: A systematic review. Turk J Phys Med Rehabil [Internet]. 2019; 65(1):[93-110 pp.]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6648185/.

34. Centre N. Cuevas Medek Exercise 2020 [Available from: https://napacentre.com.au/our-programs/intensive-therapy/.

35. Vanderminden JA. The social construction of disability and the modern-day healer 2009.

36. de Oliveira GR, Fabris Vidal M. A normal motor development in congenital hydrocephalus after Cuevas Medek Exercises as early intervention: A case report. Clinical Case Reports [Internet]. 2020; 8(7):[1226-9 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/ccr3.2860.

37. Mitroi S. Stimulation of triple extension tone and orthostatic balance in the child with cerebral palsy through exercises specific to medek method. PhysicalEducation, Sport and KinesiologyJournal [Internet]. 2016; 1(43):[48-51 pp.]. Available from: https://discobolulunefs.ro/Reviste/2016/Discobolul_fullpaper_43_1_2016_v2.pdf#page=47.

38. Tanner K, Schmidt E, Martin K, Bassi M. Interventions Within the Scope of Occupational Therapy Practice to Improve Motor Performance for Children Ages 0–5 Years: A Systematic Review. American Journal of Occupational Therapy [Internet]. 2020; 74(2):[7402180060p1-p40 pp.]. Available from: https://doi.org/10.5014/ajot.2020.039644.

39. Longo E, de Campos AC, Palisano RJ. Let's make pediatric physical therapy a true evidence-based field! Can we count on you? Brazilian journal of physical therapy [Internet]. 2019 May-Jun; 23(3):[187-8 pp.]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6531638/.

40. Sakzewski L, Ziviani J, Boyd RN. Efficacy of Upper Limb Therapies for Unilateral Cerebral Palsy: A Meta-analysis. Pediatrics [Internet]. 2014; 133(1):[e175-e204 pp.]. Available from: https://pediatrics.aappublications.org/content/pediatrics/133/1/e175.full.pdf.

41. Elgawish M, Zakaria M. The effectiveness of intensive versus standard physical therapy for motor progress in children with spastic cerebral palsy. Egyptian Rheumatology and Rehabilitation [Internet]. 2015 January 1, 2015; 42(1):[1-6 pp.]. Available from: http://www.err.eg.net/article.asp?issn=1110-161X;year=2015;volume=42;issue=1;spage=1;epage=6;aulast=Elgawish.

42. Novak I, Cusick A, Lannin N. Occupational Therapy Home Programs for Cerebral Palsy: Double-Blind, Randomized, Controlled Trial. Pediatrics [Internet]. 2009; 124(4):[e606-e14 pp.]. Available from: https://pediatrics.aappublications.org/content/pediatrics/124/4/e606.full.pdf.

43. Lin K-c, Wang T-n, Wu C-y, Chen C-l, Chang K-c, Lin Y-c, et al. Effects of home-based constraint-induced therapy versus dose-matched control intervention on functional outcomes and caregiver well-being in children with cerebral palsy. Research in Developmental Disabilities [Internet]. 2011 2011/09/01/; 32(5):[1483-91 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S0891422211000242.

44. Eliasson A-C, Shaw K, Berg E, Krumlinde-Sundholm L. An ecological approach of Constraint Induced Movement Therapy for 2–3-year-old children: A randomized control trial. Research in Developmental Disabilities [Internet]. 2011 2011/11/01/; 32(6):[2820-8 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S089142221100196X.

45. Hoare B, Imms C, Villanueva E, Rawicki HB, Matyas T, Carey L. Intensive therapy following upper limb botulinum toxin A injection in young children with unilateral cerebral palsy: a randomized trial. Developmental Medicine & Child Neurology [Internet]. 2013; 55(3):[238-47 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/dmcn.12054.

46. Rosenbaum PL, Walter SD, Hanna SE, Palisano RJ, Russell DJ, Raina P, et al. Prognosis for Gross Motor Function in Cerebral PalsyCreation of Motor Development Curves. JAMA [Internet]. 2002; 288(11):[1357-63 pp.]. Available from: https://doi.org/10.1001/jama.288.11.1357.

47. Holmefur M, Krumlinde-Sundhold L, Bergstrom J, Eliasson A-C. Longitudinal development of hand function in children with unilateral cerebral palsy. Developmental Medicine & Child Neurology [Internet]. 2010; 52(4):[352-7 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1469-8749.2009.03364.x.

48. Haley SM. Pediatric Evaluation of Disability Inventory (PEDI): Development, standardization and administration manual: Therapy Skill Builders; 1992.

49. Palisano RJ, Hanna SE, Rosenbaum PL, Russell DJ, Walter SD, Wood EP, et al. Validation of a Model of Gross Motor Function for Children With Cerebral Palsy. Physical Therapy [Internet]. 2000; 80(10):[974-85 pp.]. Available from: https://doi.org/10.1093/ptj/80.10.974.

50. Hanna SE, Bartlett DJ, Rivard LM, Russell DJ. Reference Curves for the Gross Motor Function Measure: Percentiles for Clinical Description and Tracking Over Time Among Children With Cerebral Palsy. Physical Therapy [Internet]. 2008; 88(5):[596-607 pp.]. Available from: https://doi.org/10.2522/ptj.20070314.

51. Bushby K, Finkel R, Birnkrant DJ, Case LE, Clemens PR, Cripe L, et al. Diagnosis and management of Duchenne muscular dystrophy, part 2: implementation of multidisciplinary care. The Lancet Neurology [Internet]. 2010 2010/02/01/; 9(2):[177-89 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S1474442209702728.

52. Lurio JG, Peay HL, Mathews KD. Recognition and management of motor delay and muscle weakness in children. Am Fam Physician [Internet]. 2015 Jan 1; 91(1):[38-44 pp.]. Available from: https://www.aafp.org/afp/2015/0101/p38.html.

53. Pascual JM. Progressive Brain Disorders in Childhood. Cambridge: Cambridge University Press; 2017.

54. Jan MM, Shaabat AO. Clobazam for the treatment of intractable childhood epilepsy. Neurosciences (Riyadh) [Internet]. 2000 Jul; 5(3):[159-61 pp.]. Available from: http://www.nsj.org.sa/pdffiles/Jul00/Clobazam.pdf.

55. Jan MM. Clinical approach to children with suspected neurodegenerative disorders. Neurosciences [Internet]. 2002; 7(1):[2-6 pp.]. Available from: https://www.researchgate.net/profile/Mohammed_Jan/publication/227859386_Clinical_approach_to_children_with_suspected_neurodegenerative_disorders/links/09e414fe6f11164c36000000.pdf.

56. Olney RS, Doernberg NS, Yeargin-Allsop M. Exclusion of progressive brain disorders of childhood for a cerebral palsy monitoring system: a public health perspective. J Registry Manag [Internet]. 2014 Winter; 41(4):[182-9 pp.]. Available from: https://pubmed.ncbi.nlm.nih.gov/25803631.

57. Christiansen AS, Lange C. Intermittent versus continuous physiotherapy in children with cerebral palsy. Developmental Medicine & Child Neurology [Internet]. 2008; 50(4):[290-3 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1469-8749.2008.02036.x.

58. Bower E, Michell D, Burnett M, Campbell MJ, McLellan DL. Randomized controlled trial of physiotherapy in 56 children with cerebral palsy followed for 18 months. Developmental Medicine & Child Neurology [Internet]. 2001; 43(1):[4-15 pp.]. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1469-8749.2001.tb00378.x.

59. Almeida KM, Fonseca ST, Figueiredo PRP, Aquino AA, Mancini MC. Effects of interventions with therapeutic suits (clothing) on impairments and functional limitations of children with cerebral

palsy: a systematic review. Brazilian Journal of Physical Therapy [Internet]. 2017 2017/09/01/; 21(5):[307-20 pp.]. Available from: http://www.sciencedirect.com/science/article/pii/S1413355517302484.

Osteopathy

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: Is osteopathy effective in improving functional outcomes for people with physical disability compared with physiotherapy?

Date: 31/10/2023

Requestor: Natasha s22(1)(a)(ii) - irrelevant material

Endorsed by: Katrin s22(1)(a)(ii) - irreleva

Researcher: Aaron s22(1)(a)(ii) - irrelevant ma

Cleared by: Stephanie s22(1)(a)(ii) - irrelevant mat

1. Contents

2. Summary

Osteopathy is an allied health profession focussing on treatment of pain and dysfunction caused by musculoskeletal conditions. It is classed as a traditional or complimentary therapy by the World Health Organisation.

There is low or very low quality evidence that osteopathic techniques are more effective in reducing pain and improving function for people with pain-related conditions compared to standard treatment such as physiotherapy, exercise or medication. Evidence is inconsistent regarding treatment of children and non-pain related conditions.

Assessments of the quality of the literature vary. Some reviews suggest moderate quality evidence exists for the effectiveness of osteopathic manipulative treatment in reducing pain and improving function. However, the methodological quality of these reviews is low.

3. Osteopathy Scope of Practice

Osteopathy is an area of traditional or complementary medicine that uses manual techniques to diagnose and treat mostly neuro-musculoskeletal and pain-related complaints (Osteopathy Australia, 2023; WHO, 2019). Osteopathy is said to take a holistic approach to diagnosis and treatment:

> Osteopathy is holistic in the sense that health, disease, and functional impairment are multi-factorial, and an osteopath considers a client's needs and goals in the relevant biopsychosocial context. This applies equally for prevention, diagnosis or therapeutic management (Osteopathy Australia, 2023, p.2).

Osteopathy is a discipline rather than a single technique and so practitioners can employ a variety of manual techniques, some of which overlap with the practices of physiotherapists and chiropractors (Steel, 2018). They may use common manual therapy techniques such as soft tissue techniques, manipulation or mobilisation. Osteopaths may also prescribe exercise, complete referrals or provide advice about lifestyle changes and available services (Osteopathy Australia, 2023). **Table 1** details techniques and treatment strategies in use by Australian osteopaths. Previous TAPIB research, RES 322 Manual therapy to address neuromusculoskeletal function, contains further consideration of manual techniques.

Osteopathic practice in Australia focusses on musculoskeletal conditions, especially related to treatment of pain conditions (Osteopathy Australia, 2023; Adams et al, 2018; Steel, 2018). Practitioners frequently treat people with sports injuries, people with work-related injuries and pregnant women. Around 12% of Australian osteopaths treat non-musculoskeletal conditions (Adams et al, 2018).

In Australia, osteopaths are university-trained allied health professionals. Osteopathy is a regulated health professional regulated by the Australian Health Practitioner Regulation Agency (AHPRA). Osteopaths must be registered with the Osteopathy Board of Australia and

accredited by the Australian Osteopathic Accreditation Council (AOAC). Osteopathy Australia is Australia's peak body representing and advocating on behalf of the profession.

Table 1 % of Australian osteopaths who use specific osteopathic techniques and treatment strategies (Source: Adams et al, 2018)

Manual technique	%
Strain/Counterstain	42.4
Muscle energy techniques	79.5
High velocity low amplitude/Spinal manipulation	63.8
Peripheral joint manipulation	39.7
Soft tissue	85.7
Myofascial release	61.8
Cranial techniques	23.5
Facilitated positional release	16.8
Needling techniques/acupuncture	23.6
Visceral techniques	9.9
Lymphatic pump	8.5
Autonomic balancing	15.9
Biodynamic techniques	15.6
Functional techniques	27.3
Balanced ligamentous tension/Ligamentous articular strain	35.2
Exercise prescription	74
Chapmans reflexes	2.4
Shockwave therapy	1.8

Manual technique	%
Ultrasound therapy	2.7
TENS or other electrotherapy	1.9
Instrument-assisted manipulative techniques	0.2
Instrument-assisted soft tissue mobilisation	1.2
Trigger point therapy	26.1
Sports taping	12.3

3.1 Osteopathy and evidence-based practice

Osteopathy is based on the following principles:

- the body is one unit of function
- the body has self-regulating mechanisms
- the body's structure and function are reciprocally inter-related (Osteopathy Australia, 2023).

Osteopathy Australia states that these principles are used together with current medical knowledge and that "scientific plausibility and evidence-informed reasoning are fundamental to diagnosis, treatment and case management" (Osteopathy Australia, 2023, p.2). Contemporary researchers have questioned whether these principles are scientifically justifiable and whether osteopathy has sufficiently incorporated evidence-based practice (Thomson & MacMillan, 2023; Skinner et al, 2022; Steel, 2018).

A 2018 survey of 992 Australian osteopaths found 75% of respondents agree that research has a moderate to high impact on their clinical practice (Adams et al, 2018). A 2019 survey of 332 Australian osteopaths found that most respondents considered evidence-based practice to be beneficial for patients, useful for clinicians and necessary for the discipline (Leach et al, 2019). In contrast, the same survey also found that most practitioners either do not engage in evidence-based practice or do so only infrequently. This is supported by a 2022 survey of 116 Australian osteopaths, which found 71% never, rarely or only sometimes considered the evidence-base for a particular technique (Clifford et al, 2022).

3.2 Doctors of Osteopathy

In most regions internationally, osteopathy is an allied health profession. In the United States, osteopathy is taught in some medical schools as part of a complete medical degree. Graduates of osteopathic schools of medicine are Doctors of Osteopathy (DO). Their

education includes training in osteopathic manual techniques and may include an emphasis on preventive care (American Osteopathic Association, n.d.). DOs are fully qualified medical doctors and practice in all medical specialties. A recent survey showed less than half of DOs employ osteopathic techniques in their practice. Of those that do, 44% employ osteopathic techniques infrequently (Healy et al, 2021).

4. Efficacy

4.1 Quality of evidence

The literature considering osteopathic techniques is generally of low quality (Bagagiolo et al, 2022), though there is some evidence that quality is improving in recent studies (Psadzki et al, 2022). Most studies investigate pain-related conditions, reflecting current osteopathic practice.

In a bibliometric study of osteopathic research, Morin and Gaboury (2021) found that most studies are published in osteopathy-focussed journals rather than general medical or allied health journals.

4.2 Osteopathy for children

Bagagiolo et al (2022) found limited or inconclusive evidence that OMT could be beneficial in the treatment of paediatric conditions. Psadzki et al (2022) reviewed 13 studies and found that OMT has little or no effect on reducing the length of hospital stay of preterm infants or improving breastfeeding. Results were inconsistent for other conditions such as asthma, ADHD, otitis media, colic and headache.

Osteopathy Australia released a position statement on the use of osteopathy for children. They state:

> Osteopathy Australia recommends that spinal manipulative techniques not be used on babies, infants or children aged under 12 years, given limited systematic evidence of clinical benefit for these patient groups. Further considerable public and regulatory concern has been raised in relation to the practice…
>
> A range of other clinical management approaches can be used to encourage range of movement, physical mobility and age-appropriate skill growth while managing potential clinical risk. Where relevant to a differential diagnosis, management options could include soft tissue manual therapy approaches, positional or postural advice, aids, toy or appliance prescription, play activity prescription and/or exercise programming (Osteopathy Australia, 2022).

4.3 Pain related conditions

There is evidence that manual therapy techniques 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. Refer to RES 322 Manual therapy to address neuromusculoskeletal function for more information around the efficacy of manual therapy in general. This section will consider the efficacy of specific osteopathic manual techniques or manual therapy performed by an osteopath.

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.

Rehman et al (2020) reviewed 16 randomly controlled trials into the effectiveness of OMT in patients with non-specific cancer pain. They found moderate quality in favour of OMT in reducing pain, disability and improving quality of life compared to control treatments including exercise, physiotherapy and medication.

In their scoping review, Jara Silva et al (2022) found all included studies showed benefit of OMT in at least one measure. However, the authors did not consider risk of bias or others measures of the quality of included studies.

Dal Farra et al (2021) reviewed 10 studies of osteopathic techniques for the treatment of chronic non-specific low back pain, including osteopathic manipulative treatment (OMT), myofascial release, craniosacral treatment and osteopathic visceral manipulation. The authors found moderate-quality evidence in favour of myofascial release compared to control treatment in the reduction in pain, but very low-quality evidence for its effectiveness in improving functional status. They also found low quality evidence in favour of OMT for pain reduction and improvement in functional status.

Bagagiolo et al (2022) assessed Rehman et al (2020) and Dal Farra et al (2020) as providing low quality evidence. All primary studies included in Rehman et al (2020) and Dal Farra et al (2020) were rated at high risk of bias. Bagagiolo et al reviewed nine systematic reviews investigating the effectiveness of OMT. They found evidence of possible reduction in pain and improvement in functional status for people with lower back and neck pain and in chronic non-specific cancer pain after OMT. They found limited or inconclusive evidence that OMT could be beneficial in the treatment of migraine or tension headache. However, Bagagiolo et al also noted that all included systematic reviews were low or critically low quality.

Bagagiolo et al (2022) found limited or inconclusive evidence that OMT could be beneficial in the treatment of irritable bowel syndrome. A more recent review presents similar results. Buffone et al (2023) found low or very low-quality evidence that OMT could improve pain and constipation associated with irritable bowel syndrome.

5. References

Adams, J., Sibbritt, D., Steel, A., & Peng, W. (2018). A workforce survey of Australian osteopathy: analysis of a nationally representative sample of osteopaths from the Osteopathy Research and Innovation Network (ORION) project. *BMC health services research*, *18*(1), 352. https://doi.org/10.1186/s12913-018-3158-y

American Osteopathic Association. (n.d.). *What is a DO?* https://osteopathic.org/what-is-osteopathic-medicine/what-is-a-do/

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

Buffone, F., Tarantino, A. G., Belloni, F., Spadafora, A., Bolzoni, G., Bruini, I., Bergna, A., & Vismara, L. (2023). Effectiveness of Osteopathic Manipulative Treatment in Adults with Irritable Bowel Syndrome: A Systematic Review and Meta-Analysis. *Healthcare (Basel, Switzerland)*, *11*(17), 2442. https://doi.org/10.3390/healthcare11172442

Clifford, A., Segal, A., Guterres, A., & Orrock, P. J. (2022). An exploration of the clinical reasoning used by registered osteopaths in their choice of therapeutic approach. *International Journal of Osteopathic Medicine*, 46, 19-28. https://doi.org/10.1016/j.ijosm.2022.10.003

Dal Farra, F., Risio, R. G., Vismara, L., & Bergna, A. (2021). Effectiveness of osteopathic interventions in chronic non-specific low back pain: A systematic review and meta-analysis. *Complementary therapies in medicine*, 56, 102616. https://doi.org/10.1016/j.ctim.2020.102616

Healy, C. J., Brockway, M. D., & Wilde, B. B. (2021). Osteopathic manipulative treatment (OMT) use among osteopathic physicians in the United States. *Journal of osteopathic medicine*, *121*(1), 57–61. https://doi.org/10.1515/jom-2020-0013

Jara Silva, C. E., Joseph, A. M., Khatib, M., Knafo, J., Karas, M., Krupa, K., Rivera, B., Macia, A., Madhu, B., McMillan, M., Burtch, J., Quinonez, J., Albert, T., & Khanna, D. (2022). Osteopathic Manipulative Treatment and the Management of Headaches: A Scoping Review. *Cureus*, *14*(8), e27830. https://doi.org/10.7759/cureus.27830

Leach, M. J., Sundberg, T., Fryer, G., Austin, P., Thomson, O. P., & Adams, J. (2019). An investigation of Australian osteopaths' attitudes, skills and utilisation of evidence-based practice: a national cross-sectional survey. *BMC health services research*, *19*(1), 498. https://doi.org/10.1186/s12913-019-4329-1

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

Morin, C., & Gaboury, I. (2021). Osteopathic empirical research: a bibliometric analysis from 1966 to 2018. *BMC complementary medicine and therapies*, *21*(1), 196. https://doi.org/10.1186/s12906-021-03366-3

Osteopathy Australia. (2023). *Statement of Scope of Practice in Osteopathy*. https://osteopathy.org.au/article/osteopathy-scope-of-practice

Osteopathy Australia. (2022). *Position statement: osteopathic clinical management for babies, infants, and children*. https://osteopathy.org.au/article/position-statement--osteopathic-clinical-management-for-babies--infants--and-children

Posadzki, P., Kyaw, B. M., Dziedzic, A., & Ernst, E. (2022). Osteopathic Manipulative Treatment for Pediatric Conditions: An Update of Systematic Review and Meta-Analysis. *Journal of clinical medicine*, *11*(15), 4455. https://doi.org/10.3390/jcm11154455

Rehman, Y., Kirsch, J., Wang, M. Y., Ferguson, H., Bingham, J., Senger, B., Swogger, S. E., Johnston, R., & Snider, K. T. (2022). Impact of osteopathic manipulative techniques on the management of dizziness caused by neuro-otologic disorders: systematic review and meta-analysis. *Journal of osteopathic medicine*, *123*(2), 91–101. https://doi.org/10.1515/jom-2022-0119

Skinner, D., Esber, T., & Walkowski, S. (2022). Evocations of Osteopathy's founder and questions for contemporary osteopathic professional identity: A thematic analysis. International Journal of Osteopathic Medicine, 46, 1-5. https://doi.org/10.1016/j.ijosm.2022.08.001

Steel, A. (2018). Does osteopathy work? *The Conversation*. https://theconversation.com/does-osteopathy-work-98848

Thomson, O. P., & MacMillan, A. (2023). What's wrong with osteopathy? *International Journal of Osteopathic Medicine*, 48, 100659. https://doi.org/10.1016/j.ijosm.2023.100659

World Health Organization. (2019). *WHO global report on traditional and complementary medicine*. World Health Organization. https://iris.who.int/handle/10665/312342

Research Request – Delivery of Speech Pathology Support via Telehealth

Brief	Can telehealth deliver effective outcomes for the delivery of Speech Pathology support for a participant using Augmentative and Alternative communication (AAC) – low tech (e.g.PODD) vs face to face SP supports plus travel? *Particularly interested in the AAC aspect, as the participant will have complex communication needs and is most likely non-verbal. Include info re communication partner training*
Date	20/07/2020
Requester	Naomi [redacted] (Naomi [redacted] (AAT Senior Technical Advisor) Shannon [redacted] Assistant Director – TAB)
Researcher	Jane [redacted] (Research Team Leader)
Cleared by	Jane [redacted] (Research Team Leader)

Contents

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

Summary

- There is an immense amount of literature which investigates the effectiveness of speech-language pathology delivered via tele-health/tele-rehabilitation/tele-practice
    - All systematic reviews find it to be feasible and provide comparable results to in-person therapy

- Empirical research utilizing tele-practice for consultation, supervision and fieldwork in AAC is limited (mainly cover high tech AAC)
    - Preliminary case studies have found it to be a valid and appropriate service delivery method for individuals in need of AAC intervention
    - High speed internet connect is vital to success
    - Some face-to-face sessions may still be required, especially during initial consults to determine appropriate AT devices

- Communication partners that are well trained and understand the participant are critical for those who rely on AAC
    - Early research has shown training can be delivered remotely

Speech Pathology Support Delivered via telehealth

Telehealth delivered speech-language pathology (SLP) has previously been investigated in literature reviews across various practice areas and populations. Below is a summary of findings from these reviews.

Mashima and Doarn (2008) [1] conducted an extensive literature review on the application of telehealth in SLP with adults and a small number of studies with children.

- Reviewed 40 studies investigating disorders relating to adult neurogenic communication, fluency, voice, dysphagia (n=35), and childhood speech and language (n=5).
- Suggested that telehealth is a feasible and effective method for providing SLP services at a distance
- Authors noted that the reviewed literature consisted primarily of pilot studies and anecdotal accounts of telehealth applications rather than large, well-controlled, randomised clinical trials

Reynolds, Vick, and Haak (2009) [2] conducted a narrative review of 29 studies which were analysed using a quality assessment checklist.

- Articles focused on assessment and intervention with the adult (n=19) and paediatric (n=7) population as well as an unspecified population (n=3)
- Authors concluded that the results achieved through the **telehealth and in-person service delivery models were equivalent**
- Many of the studies noted that telehealth was not a complete replacement for in-person services but may be appropriate for combined practices.

Edwards, Stredler-Brown, and Houston (2012) [3] conducted a further review investigating 39 studies in the fields of audiology and SLP.

- Majority of studies conducted on adult populations (n=27) with neurogenic communication, voice, dysphagia and fluency disorders
- Review expanded to include a small number of studies (n=12) focusing on early intervention services.
- Concluded that telehealth is an effective way to diagnose and treat both adults and children in the areas investigated, as **services provided through telehealth or by conventional in person means resulted in similar outcomes**

A more recent review focusing on the efficacy of telehealth delivered SLP services compared to traditional in-person delivery for primary school aged children with speech and/or language difficulties was conducted by Wales, Skinner, Hayman (2017) [4].

- 7 studies met inclusion criteria (2 RCT, 2 comparison studies, 3 pre- vs post intervention studies)
- Number of sessions ranged from 6-12 (delivered fortnightly)
- Convincing evidence that speech sound intervention delivered through telehealth to primary school age children was **just as effective as in-person intervention**
- Overall, whilst the studies revealed that intervention delivered through telehealth is as effective as in-person intervention, this result seemed to be found more consistently with

the provision of speech sound intervention than with language intervention (due to more studies focusing on speech sound interventions)
- Limitations: Most studies were of poor methodological quality, small and unequal sample sizes lack of random allocation

Delivery of telehealth to those with Augmentative and Alternative communication

Empirical research utilizing tele-practice for consultation, supervision and fieldwork in AAC is limited. The current literature in this space is summarised below.

LoPresti, Jinks, Simpson (2015) [5] investigated whether individuals could obtain appropriate prescriptions for computer-based assistive technology through the use of a tele-rehabilitation (TR) system.

- Study utilised VISYTER which is a web-based TR portal and integrated videoconferencing system based on cost-effective, open-source software
    - It allows for one site to send multiple video streams. For example, it is possible to transmit a view of the consumer's face and a second view of the consumer's hands on a keyboard, or a view of the consumer's posture and a second view of an AAC device screen
- 66 AAC participants were recruited and split across 3 groups
    - Control = received all services with an assistive technology specialist physically present
    - Mixed = initial assessment with the assistive technology specialist physically present and all remaining services remotely
    - Remote = received all services remotely
- Participants reported high satisfaction with TR services, and similar satisfaction with their overall AT service experience compared with consumers who received exclusively in-person services.
- Limitations of TR = lack of consistent high-bandwidth Internet connections, need for equipment and staff resources at the client location (especially during an initial evaluation), and TR visual and multi-tasking demands on the clinician.
- **TR might be most practical for follow-up sessions after an initial, in-person evaluation**, or in situations when **a support person with sufficient expertise can be physically present with the participant.**

A descriptive study as part of a Master's Thesis by Vaughan (2018) [6] implemented low technology AAC boards to two children in Peru and conducted maintenance appointments using telehealth.

- Implementation of AAC consisted of 4 days of intervention sessions with durations between 30 minutes to 1 hour.
- Four maintenance sessions for each participant were conducted through tele-practice on Skype for Business
- Participant 1: Progressed and surpassed, mastered, and had emerging communication skills.
- Participant 2: Due to technological difficulties (i.e., poor Internet connection) it was uncertain if communication was improved
    - When the parent was questioned, it was noted that the participant was developing a more efficient and effective means to consistently say *yes* or *no* with familiar and unfamiliar communication partners.

- In conclusion, tele-practice were easy to use and overall outcomes were positive.

Fissel, Mitchell and Alvares (2015) [7] present a case study of a 6 year-old boy with neurological impairments and a limited range of communication behaviours including mostly unintelligible single-world verbalisations, vocalisations and occasional gestures.

- The authors adapted an assessment model to assess the literacy skills of the participant using telehealth as no AAC specialists were available in the area
- Concluded that telehealth appears to be feasible with the potential to assess, intervene with, and meet the diverse needs of children with complex communication needs
    - Particularly those with limited access to ACC specialists

A further case study presented by Hall, Boisvert and Jellison [8] utilised 4 participants using a single subject, multiple baseline design to monitor the progress of student participants and compare outcome data when services were provided on-site or via tele-practice.

- No significant difference between the number of unprompted and prompted targets generated by participants when receiving services onsite as compared to the matched participants receiving services through tele-AAC
- Provides empirical evidence in support of tele-practice as a valid and appropriate service delivery method for individuals in need of AAC intervention

Three case studies are presented by Curtis (2014) [9].
Case 1: 50 year old woman with cerebral palsy with experience using speech generating device

- Participant was able to learn new program (E Z Keys) over tele-consultation to operate the mouse, open and close programs, browse the web, email, and text message.

Case 2: Experienced speech generating device user who has been living with ALS for many years

- Participant able to develop eye gaze skills with no assistance from carer or wife

Case 3: 50+ year old woman with cerebral palsy who had never had a formal communication system

- After weekly sessions for 12 months the participant was able demonstrate for the first time the ability to communicate novel information of her own choosing.
- She became a context dependent communicator who can communicate some information in some settings with a familiar and supportive communication partner

Communication Partner Training

It is important for communication partners (e.g., caregivers and educators) to receive training on how to provide interventions. Communication partners should be incorporated in intervention training to further improve the language and communication outcomes for individuals with complex communication needs [10].

Various systematic reviews investigating the effect of communication partner training have found similar results across various participants groups requiring AAC;

- Communication partner interventions were found to be highly effective across a range of participants using AAC, intervention approaches, and outcome measure characteristics, with more evidence available for participants less than 12 years of age, most of whom had a diagnosis of autism spectrum disorder or intellectual/developmental disability [11].
- 56 studies across 2 systematic reviews have reported positive outcomes from communication partner training in aphasia [12].
    - partner training should be conducted to improve partner skill in facilitating the communication of people with chronic aphasia

- Intervention research designed to support communication partners provides positive preliminary evidence for partners' adoption of strategies to support children using AAC [13].

Communication partner training using telehealth

Quinn, Beukelman and Thiessen (2011) [14] evaluated the accuracy of an instructional strategy for potential AAC facilitators to operate and maintain high technology AAC device software using Remote Access Error-Free (RA-EF) instruction.

- Participants in this study were graduate students in speech-language pathology
- Following fewer than 30 minutes of instruction focusing on 11 operational skills, a group of 10 participants who were unfamiliar with the Visual Scenes Display for Aphasia application (Version 2) achieved post-instruction accuracy scores of 98.2%

Timpe, E., Kent-Walsh, J., Harrington, N., Lavadia, L., & Vazquez (2016) [15] designed and delivered the 'iCan Communicate' program which is a parent focused AAC intervention program. The program was delivered over 9 sessions via face-2-face and tele-practice services.

Results indicated:

- High parent satisfaction with the service delivery model
- Increased accuracy of parent application of the targeted interaction strategy
- Increased frequency and diversity in the children's multi-modal communicative turn taking

Reference List

1. Mashima PA, Doarn CR. Overview of telehealth activities in speech-language pathology. Telemedicine and e-Health. 2008 Dec 1;14(10):1101-17.
2. Reynolds AL, Vick JL, Haak NJ. Telehealth applications in speech-language pathology: A modified narrative review. Journal of Telemedicine and Telecare. 2009 Sep;15(6):310-6.
3. Edwards, M., Stredler-Brown, A., & Houston, K. T. (2012). Expanding use of telepractice in speech-language pathology and audiology. Volta Review, 112, 227-242.
4. Wales D, Skinner L, Hayman M. The efficacy of telehealth-delivered speech and language intervention for primary school-age children: a systematic review. International Journal of Telerehabilitation. 2017;9(1):55.
5. LoPresti EF, Jinks A, Simpson RC. Consumer satisfaction with telerehabilitation service provision of alternative computer access and augmentative and alternative communication. International journal of telerehabilitation. 2015;7(2):3.
6. Vaughan LE. *The Development, Implementation, and Maintenance of Augmentative and Alternative Communication Through Telepractice in Peru* (Doctoral dissertation, University of Kansas).
7. Fissel SN, Mitchell PR, Alvares RL. An Adapted Assessment Model for Emergent Literacy Conducted via Telepractice. Perspectives on Telepractice. 2015 Sep;5(2):48-56.
8. Hall N, Boisvert M, Jellison H. An Investigation of the Efficacy of Direct AAC Service Provision via Telepractice: A Case Study.
9. Curtis TR. Case studies for telepractice in AAC. Perspectives on Augmentative and Alternative Communication. 2014 Jan;23(1):42-54.
10. Kaiser, A. P., & Roberts, M. Y. (2013). Parents as communication partners: An evidence-based strategy for improving parent support for language and communication in everyday settings. *SIG 1 Perspectives on Language Learning and Education*, *20*, 96-111. DOI:10.1044/lle20.3.96.
11. Kent-Walsh J, Murza KA, Malani MD, Binger C. Effects of communication partner instruction on the communication of individuals using AAC: A meta-analysis. Augmentative and Alternative Communication. 2015 Oct 2;31(4):271-84.
12. Simmons-Mackie N, Raymer A, Cherney LR. Communication partner training in aphasia: An updated systematic review. Archives of Physical Medicine and Rehabilitation. 2016 Dec 1;97(12):2202-21.
13. Shire SY, Jones N. Communication partners supporting children with complex communication needs who use AAC: A systematic review. Communication Disorders Quarterly. 2015 Nov;37(1):3-15.
14. Quinn E, Beukelman D, Thiessen A. Remote instruction of potential AAC support personnel. Perspectives on Augmentative and Alternative Communication. 2011 Sep;20(3):97-101.
15. Timpe, E., Kent-Walsh, J., Harrington, N., Lavadia, L., & Vazquez, J. (2016). I-Can Communicate: Expanding Service Delivery Models to Include Telepractice. [Conference Proceedings]. International Society for Augmentative and Alternative Communication, 1-4. AN:120720849

Lokomat Therapy and robot assisted gait training

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: What is the efficacy of Lokomat therapy to improve gait/gross motor skills in different populations (CP, SCI, ABI)?

Is there any particular level of ability that responds more favourably to the therapy, eg in CP, does the Gross Motor Functional Classification Scale level make a difference to outcomes?

Is there any evidence for long-term efficacy, i.e. are gains maintained once therapy stops?

Is Lokomat more effective than other types of traditional physiotherapy to improve gait?

Is there any evidence of a particular intensity of Lokomat therapy being more effective, e.g. once/twice a week therapy is required?

Is there any evidence about the duration of therapy required to see meaningful and long-lasting change?

Is there any evidence whether Lokomat is more effective as a rehabilitation tool (eg soon after onset of SCI or ABI), compared to a maintenance support (more than 2 years post-onset) or an early intervention support (for children with congenital conditions)?

Date: 22/12/2022

Requestor: Jean s22(1)(a)(ii) - irrelevant

Endorsed by: Jane s22(1)(a)(ii) - irrelev

Researcher: Aaron s22(1)(a)(ii) - irrelevant ma

Cleared by: Aaron s22(1)(a)(ii) - irrelevant ma

Review date: 6/2024

1. Contents

2. Summary

This paper examines evidence of efficacy for the use of the Lokomat device in improving gait and motor function in people with Cerebral Palsy (CP), Multiple Sclerosis (MS), Parkinson's disease, Spinal Cord Injury (SCI) and stroke. Most reviews combine results for Lokomat and other types of robot assisted gait training (RAGT). I have noted where results could be separated.

Due to the large body of evidence, I have based conclusions on mostly systematic reviews. There are certainly primary or other secondary studies which were not accounted for in this research which may inform different conclusions.

RAGT is generally shown to be effective in improving some measures of gait and motor function for the populations reviewed. However, studies disagree on whether RAGT is independently effective or should be combined with other physiotherapy treatments. Evidence is weaker in some areas. For example, we were only able to find two systematic reviews for the use for RAGT for people with Parkinson's disease, and both reviews were completed by the same team of researchers. Other conditions are more thoroughly researched. For example, there is a significant body of evidence regarding use of RAGT in stroke patients.

Despite some lack of clarity, the best evidence suggests RAGT improves stroke patient's chance of independent mobility if delivered within the first 3 months after injury.

Most reviews did not draw conclusions regarding the long-term efficacy of RAGT. One study was able to show that positive effects last for young people with CP up to 3 months post intervention. However these results are not conclusive.

There is some evidence that RAGT could be more effective for people with more significant impairment. Reviews often discuss the specific benefits of robotic exoskeleton assistance for people who cannot walk independently. However these results are not conclusive.

Studies were generally unable to establish appropriate dosage. However, treatment frequency and duration was generally 2 – 5 times per week for 30 – 45 minutes.

Lokomat is considered safe. There is a record of adverse events those these are typically minor bruising or muscle pain.

For detailed consideration of efficacy, refer to individual sections in 4. Evidence for different conditions.

3. Lokomat therapy

3.1 Robot assisted gait training

There are two main distinctions separating different types of RAGT device. Devices can be stationary or ambulatory, meaning the device is either fixed (usually to a treadmill) or unfixed. Unfixed, ambulatory devices allow users to walk around in more typical ways and perform different activities such as sitting or squatting. Stationary RAGT devices are further divided between exoskeleton and end-effector type devices. Users of stationary exoskeleton devices wear a lower limb exoskeleton. Users of end-effector devices have robotic 'arms' attached to their feet to move their lower limb on preestablished paths. The Lokomat is a model of stationary exoskeleton RAGT device (Bessler et al, 2020).

Exoskeleton-type devices are more common in the literature than end-effector type devices (Calabro et al, 2021b; Bowman et al, 2021). Lokomat is the most common type of stationary exoskeleton RAGT device (Calafiore et al, 2022; Llamos-Ramos et al, 2022; Calabro et al, 2021b; Cumplido et al, 2021). For example, in a review from Calabro et al (2021), all stationary exoskeleton studies (13 in total) used the Lokomat. In a review from Carvalho et al (2017), nine out of 10 studies used the Lokomat.

Only one systematic review found compared use of Lokomat with other RAGT devices (Zhang et al, 2022). Most reviews suggest that there is insufficient data to directly compare the effectiveness of different RAGT devices (Name et al, 2017; Hayes et al, 2018; Llamos-Ramos et al, 2022).

3.2 Dosage

Calabrò et al (2021a) note that there is no consensus on protocols for treatment of people lower limb motor function in people with stroke. Timing, frequency, training session duration and the characteristics of those who could benefit are still disputed. Mehrholz et al (2020) were also unable to determine dosage for people with symptoms of stroke. Where reviews for other conditions attempted to establish dosage, most were unable (Bowman et al, 2021; Cumplido et al, 2021). Carvalho et al (2017) find benefits in young people with CP where frequency of training was at least 4 days per week with a duration of at least 30 minutes.

Across all reviews, sessions frequency was usually 30-45 minutes for 2 – 5 times per week.

3.3 Time after injury

Clinical practice guidelines for treatment of people with stroke, SCI or TBI suggest that RAGT should not be offered to improve walking speed or distance in ambulatory patients after 6 months since the injury occurred (Hornby et al, 2020). Mehrholz et al (2020) found some evidence suggesting effect was greater for patients who receive treatment within 3 months of injury. Nam et al (2017) found some evidence of improvement in patients with SCI even at 1 year post-injury.

4. Evidence for different conditions

4.1 Spinal cord injury

Six systematic reviews between 2019 and 2022 have examined the use of RAGT by people with SCI. All reviews report limitations including heterogeneity of study designs and treatment protocols which make summarising effects difficult (Zhang et al, 2022).

Nam et al (2017) reviewed 10 studies describing a total of 502 people with incomplete spinal cord injury with the aim of assessing the effects of RAGT on improvement in walking related functional outcomes. They found mobility-related outcomes (walking distance, lower limb strength, functional mobility and independence) improved to a greater extent with RAGT compared to typical over-ground training for people who received treatment within 6 months of their spinal cord injury. For people who received RAGT at least one year after their injury, treatment improved gait speed and balance compared to no treatment, but no difference was found for improvements in gait distance, leg strength or functional mobility and independence when compared with over-ground training.

Hayes et al (2018) reviewed 12 studies describing a total of 512 participants, 496 with either complete or incomplete SCI and 16 with no injury. The authors found inconsistent evidence around walking speed and walking distance. No evidence reviewed by Hayes et al suggests that use of RAGT can improve walking speed or to a sufficient degree to facilitate community ambulation. The authors conclude that RAGT is likely an effective companion treatment for people with both complete and incomplete SCI when used in conjunction with other therapies.

Aguirre-Güemez et al (2019) included 20 studies in their systematic review of the efficacy of RAGT on gait, strength and functioning in people with incomplete SCI. Six of those studies, representing 222 participants were included in the meta-analysis. Good quality evidence shows a moderate effect of RAGT on strength, and a large effect on gait and functioning. There was no effect for walking speed.

Fang et al (2020) reviewed 7 RCTs and 11 other studies of varied designs to assess the effects of RAGT on walking ability, spasticity and pain in people with SCI. The authors suggest RAGT can decrease spasticity and improve walking ability but they found no effect on pain. However, results are complicated by separately pooled RCT and non-RCT studies. For example, while results of non-RCTs showed a significant reduction in spasticity after treatment, RCTs did not show the same effect.

Two systematic reviews investigated Lokomat specifically (Alashram et al, 2021; Zhang et al, 2022). Alashram et al (2021) reviewed 16 studies representing 658 people with incomplete SCI. They found the Lokomat may improve gait speed, walking distance, strength, range of motion and mobility. However, the authors suggest Lokomat is no better than over-ground training or bike interventions at improving gait speed. Lokomat combined with conventional physiotherapy may be superior to over-ground training and conventional therapy for improving mobility, walking distance and muscle strength. Alashram et al found insufficient evidence for effects on balance, and non-mobility related outcomes such as depression, cardiorespiratory fitness and quality of life.

Zhang et al (2022) is the only systematic review to compare the effectiveness of Lokomat with other RAGT devices. In this case, the authors compared Lokomat as a stationary RAGT device, with a variety of ambulatory RAGT devices (Ekso, HAL, Indego, REX, ReWalk, and SMA). Most of the participants in the ambulatory RAGT studies had complete SCI, whereas most of the participants in the Lokomat studies had incomplete SCIs. This could suggest benefits of the devices for different populations, however there is insufficient evidence to rely on this judgement. While both types of device improved walking distance, speed and function, the authors conclude that ambulatory RAGT devices are more effective than Lokomat in stimulating muscle activity and may be more cost-effective. Cost-effectiveness was not a targeted outcome of the study and so conclusions regarding this preference for ambulatory RAGT devices should not be relied upon.

Zhang et al is significant as the only review to compare different types of RAGT devices. However there are some quality issues which suggest we should treat the results with caution. For example, the number of studies reviewed is reported differently in different places in the report with no explanation.

4.2 Stroke

Use of RAGT technology for stroke patients is growing and a significant body of research investigates the use of RAGT for people who have experienced stroke. Calabrò et al (2021a) note a discrepancy between the implementation of RAGT for stroke patients and the research that supports this. In contrast, Mehrholz et al (2020; 2021) assert with a high degree of confidence that RAGT in combination with conventional treatment can support stroke patients to walk independently. The weight of evidence so far supports the use of RAGT for stroke patients up to 3 months after injury.

Evidence does not so far support the use of RAGT for patients in the chronic stage of stroke (Calabrò et al, 2021a; Hornby et al, 2020; Mehrholz et al, 2020). However, evidence is emerging for the use of RAGT in combination with conventional therapy for patients in the acute or sub-acute stages of injury. Calabrò et al (2021a) note evidence that RAGT can improve chances of independent gait in people with more severe impairments and in early stages of recovery, especially when combined with other treatments. From a review of 13 papers, Baroncheli et al (2021) produced positive results for improvements in balance after treatment using Lokomat. The largest review to date (Mehrholz et al, 2020; Mehrholz et al, 2021), including 62 studies and 2440 patients, found with a high degree of confidence that patients who receive RAGT in combination with conventional treatment are more likely to achieve independent walking than patients who receive gait training without the robotic device. They also note less certain evidence that the effect is more pronounced for people who receive treatment within 3 months of injury.

However, other reviews provide more mixed evidence. Lorusso et al (2022) focus on ambulatory RAGT device (not Lokomat) and find that use of these devices does not improve balance or activities of daily living more than conventional treatment. Nedergård et al (2021) found mixed results of low certainty in a review of 13 papers investigating the effect of RAGT on biomechanical measures of gait. They found no significant difference from conventional therapy for gait speed, cadence, spatial asymmetry and step length on the non-affected side. There were slight improvements over conventional therapy for stride length, step length on the affected side and temporal asymmetry calculated in ratio values. Calafiore et al (2022) show that while RAGT combined with conventional treatment can be effective in improving gait for people who have experienced stroke within 6 months, it has not been demonstrated that it is superior to conventional treatment alone. Only one out of the 9 Lokomat RCTs that Calafiore et al reviewed showed a significant improvement of RAGT with conventional treatment compared to conventional treatment alone. Three RCTs showed superiority of conventional treatment compared with RAGT alone and six RCTs showed no significant difference between RAGT combined with conventional treatment and conventional treatment alone.

The discrepancy between Nedergård et al (2021) and Calafiore et al (2022) on the one hand, and the more comprehensive study from Mehrholz et al (2020;2021) could be related to smaller samples and lower quality studies for Nedergård et al and Calafiore et al. It could also relate to failure to separate out sub-groups (ambulatory, non-ambulatory) or differing

definitions of chronicity. Calafiore et al (2022) group patients receiving treatment before 6 months after injury, whereas Mehrholz et al (2020; 2021) define chronicity as 3 months post-injury.

4.3 Multiple Sclerosis

Five systematic reviews between 2019 and 2022 have examined the use of RAGT by people with MS.

Sattelmayer et al (2019) found walking speed and level of disability (as measured by did the Expanded Disability Status Scale) were slightly but not significantly improved in RAGT compared to conventional overground walking therapy. The authors emphasise that their meta-analysis is compatible with no real difference in effect between RAGT and conventional therapy. Yeh et al (2020) found RAGT was comparable to conventional walking therapy in improving walking performance, quality of life, pain and activities of daily living. RAGT was found to be superior to conventional treatment in improving perceived fatigue, spasticity and global mobility. Bowman et al (2021) found RAGT was superior to unspecific balance and gait intervention but showed similar improvements in balance, gait speed, walking ability, and stride length when compared to specific rehabilitation training programs like conventional walking training or sensory integration balance training.

Sattelmayer et al (2019) were unable to determine whether effects of RAGT depend on severity of symptoms of MS (as measured by EDSS). More recently, Calabrò et al (2021b) found RAGT was superior to other treatments in improving non-motor outcomes such as spasticity, fatigue, pain, psychological well-being and quality of life and comparable to conventional treatment for gait and mobility for users with mild to moderate symptoms of MS. However, they also found RAGT is more effective for people with more severe symptoms (EDSS 6-7.5) compared to conventional treatment.

This is further supported by Binshalan et al (2022), who found RAGT is more effective for people with severe MS compared to conventional treatment. They found that RAGT had the most supporting evidence of all physiotherapy interventions considered for this cohort. The authors did not distinguish models of RAGT devices in their review. They found statistically significant improvements in the 6 minute walk test, 10 metre walk test, Berg Balance Scale and Fatigue Severity Scale. They found no significant results on the Timed Up and Go test. Binshalan et al interpret the results on these outcome measures as suggesting RAGT can improve aerobic capacity, endurance and walking speed for people with severe MS. They also suggest RAGT is unlikely to improve capacity to transfer or sit-to-stand in people with severe MS, and therefore RAGT should be supplemented with other physiotherapy interventions. However, the authors also note that there is little evidence for the effectiveness of other physiotherapy interventions on mobility in people with severe MS.

4.4 Parkinson's Disease

There is evidence that RAGT can improve gait and motor skills in people with Parkinson's disease, though it is not clear whether RAGT is better than conventional therapy.

Alwadat and Etoon (2019) reviewed three case studies and an uncontrolled pilot study with a combined population of 26. The case studies all used the Lokomat. The pilot study did not report the type of RAGT device used. The authors found RAGT improves freezing of gait in people with Parkinson's disease. However, the authors note quality issues and low level of evidence from the included studies.

Alwadat et al (2018) reviewed 7 randomly controlled trials investigating the effectiveness of RAGT on motor impairments in people with Parkinson's Disease. Only two of the 7 studies used the Lokomat with a combined total of 68 subjects. Both Lokomat studies showed significant improvement in outcomes measure for RAGT compared to the regular exercise. However, they showed improvement in different measures. One study showed significant improvement in the 10-metre walk test (10mWT) and Unified Parkinson Disease Rating Scale Part III (UPDRS-III). The other did not show improvement in UPDRS-III but did show improvement in 10mWT and the Timed Up and Go (TUG) test.

Across all seven studies, RAGT was significantly better than regular exercise or treadmill training according to UPDS-III, Berg Balance Scale, 10mWT, and stride length. Significant results were not found for TUG, stride time, cadence, or Activities-Specific Balance Confidence scale. In sum, the authors conclude that RAGT can improve some gait and motor skills but that it was not shown to be superior to regular physiotherapy intervention for improving motor skills in people with Parkinson's disease.

4.5 Cerebral Palsy

Six systematic reviews between 2017 and 2022 have examined the efficacy of RAGT for people with CP. Three of the reviews only considered children and adolescents by design (Llamos-Ramos, 2022; Olmos-Gómez, 2021; Cumplido et al, 2021). Of the other three systematic reviews, the majority of participants in the majority of studies were under 18 years. Volpini et al (2022) reviews only one study with participants aged up to 19 years. Conner et al (2022) reviews one study with participants aged 15 - 35, though the other seven reviewed papers included only participants under 18 years. Carvalho et al (2017) reviews studies for participants up to the age of 21. The results reported below are likely only valid for children and adolescents and caution should be used applying them to older adult populations.

One of the first reviews of RAGT for people with CP(Carvalho et al, 2017) found suggestive evidence that RAGT could improve gait speed, endurance and gross motor function in children and young adults with CP. Benefits were found in studies where frequency of training was at least 4 days per week with a duration of at least 30 minutes. Studies which divided participants by GMFCS classification provided some evidence that RAGT is of greater benefit to people with lower GMFCS classifications (I – II) than higher (III – IV). However, due to low levels of

evidence and significant heterogeneity of sample characteristics (eg. wide variation in GMFCS classification), the authors' generalisations are not wholly reliable.

Meta-analyses from Olmos-Gomez et al (2020) and Conner et al (2022) found RAGT offers no improvement above standard care based on their reviews of RCTs. Olmos-Gomez (2020) review eight studies with a combined population of 217 subjects. Considering dimensions D and E of the GMFM, gait speed, resistance, and step length, no difference was found between RAGT and conventional physiotherapy or for RAGT combined with physiotherapy and physiotherapy alone. Conner et al (2022) reviewed eight studies with a combined population of 188 subjects. They found no improvement above conventional treatment according to the 6mWT, walking speed or GMFM dimensions D and E. Conner et al were also able to isolate an effect for the Lokomat specifically, based on 4 RCTs using the device. They found RAGT using the Lokomat was not any more effective than conventional physiotherapy treatment. Both reviews cautioned that the results of their meta-analyses may not generalise due to the heterogeneous presentation of CP and difference comparison interventions.

Llamos-Ramos (2022) and Cumplido et al (2021) found inconsistent evidence with studies showing variously no benefit, significant benefit compared to conventional treatment or equal benefit compared to conventional treatment. Llamos-Ramos conclude that while evidence does not support the use of RAGT alone, it is likely that RAGT is a useful tool to complement other therapies for children with CP. Cumplido et al (2021) agree that evidence is suggestive of some benefit to RAGT, though the authors also emphasise that the positive results may not generalise as most of the included studies represented low levels of evidence, results for different types of RAGT device were considered together and RAGT was often mixed with other interventions such as conventional walking training and virtual reality devices.

Volpini et al (2022) is the first study that reviews maintenance of effects of RAGT over the long term, defined as 3 months after treatment. They find RAGT improves walking distance in the short term and these benefits were maintained in the long term. They also found clinically but not statistically significant improvements in gait speed and gross motor function which were also maintained in the long term. However it should be noted that most of the studies reviewed had a high risk of bias and the meta-analysis considered only 77 subjects. Also, few of the studies reported on how the long term follow up was controlled, whether subjects continued use of RAGT or received other therapies during follow up.

5. Risks and contraindications

Injuries have been associated with use of RAGT devices. Bessler et al (2020) reviewed 50 studies of RAGT devices. Of those studies, 27 studies including 489 subjects investigated the Lokomat and 12 reported adverse events. Types of adverse event reported were muscle pain, joint pain, skin erythema, open skin lesions, skin abrasions, tendinopathy, discomfort, redness, giddiness, bruises, fear of device, skin irritation, proximal tibial fracture, and atypical autonomic dysreflexia. On average, there were 16.6 occurrences of adverse events per 100 subjects. The

majority of adverse events were minor soft-tissue (muscle pain, bruising, skin lesions) or musculoskeletal injuries.

Cumplido et al (2021) suggest RAGT is safe for children with CP. Their review found no reports of adverse events.

According to the manufacturer (*Legal Notes*, 2016), the following risk factors should lead to additional safety measures or may indicate that use of the Lokomat is not appropriate:

- arthroplasty (especially hip arthroplasty or arthroplasties where external hip rotation is contraindicated for the patient)
- uncontrolled hip, knee or ankle instability that would still pose a danger despite the body weight support (especially lateral instability when training with the FreeD module).
- lack of head control
- joint contractures or limitations in the range of motion due to spasticity that can't be reduced
- differences in leg length correctable with an insole
- skin lesions (including pressure sores) in areas of contact with harness support, robotic orthosis (buttocks and along lower extremities) or lower extremity loading (feet).
- sensory impairment in the lower limbs and trunk, especially reduced pain sensation
- risk of autonomic dysreflexia (level at or above T6; history of AD increases the risk of having a reoccurring episode)
- recent history or elevated risk of seizures
- cardiac conditions, e.g., cardiac insufficiency and thoracotomy, uncontrolled orthostatic hypotension or other circulatory problems, vascular disorders of the lower limbs
- uncooperative or (self-)aggressive behaviour (e.g., transitory psychotic syndrome)
- mechanical ventilation
- long-term infusions (e.g., baclofen pump, intrathecal pumps, PEG tube…) or stimulators (e.g. pacemakers, nerve stimulators).

A person should not use Lokomat if they:

- have, have had, or can be suspected of having significantly reduced bone density loss or increased risk of fractures
- are heavier than 135kg, lighter than 10kg or taller than 2m

- have an upper leg length of less than 21 cm or more than 35 cm for the paediatric orthosis or less than 35 cm and more than 47 cm for the adult orthosis
- have non-consolidated bone fracture
- fixed joint contractures that limit the range of motion of the orthosis
- any condition that prevents proper and pain-free adjustment of the harness or orthosis (e.g. pregnancy, colostomy bag, unprotected skin lesions, uncorrectable difference in leg length)
- any condition preventing active rehabilitation (e.g. respiratory disease, pregnancy, orthopedic conditions, cognitive deficits limiting communication, neuro-psychological conditions, infections or inflammatory disorders, osteomyelitis).

6. References

Aguirre-Güemez, A. V., Pérez-Sanpablo, A. I., Quinzaños-Fresnedo, J., Pérez-Zavala, R., & Barrera-Ortiz, A. (2019). Walking speed is not the best outcome to evaluate the effect of robotic assisted gait training in people with motor incomplete Spinal Cord Injury: A Systematic Review with meta-analysis. *The Journal of Spinal Cord Medicine*, *42*(2), 142–154. https://doi.org/10.1080/10790268.2017.1390644

Alashram, A. R., Annino, G., & Padua, E. (2021). Robot-assisted gait training in individuals with spinal cord injury: A systematic review for the clinical effectiveness of Lokomat. *Journal of Clinical Neuroscience: Official Journal of the Neurosurgical Society of Australasia*, *91*, 260–269. https://doi.org/10.1016/j.jocn.2021.07.019

Alwardat, M., Etoom, M., Al Dajah, S., Schirinzi, T., Di Lazzaro, G., Sinibaldi Salimei, P., Biagio Mercuri, N., & Pisani, A. (2018). Effectiveness of robot-assisted gait training on motor impairments in people with Parkinson's disease: a systematic review and meta-analysis: A systematic review and meta-analysis. *International Journal of Rehabilitation Research*, *41*(4), 287–296. https://doi.org/10.1097/MRR.0000000000000312

Alwardat, M., & Etoom, M. (2019). Effectiveness of robot-assisted gait training on freezing of gait in people with Parkinson disease: evidence from a literature review. *Journal of Exercise Rehabilitation*, *15*(2), 187–192. https://doi.org/10.12965/jer.1836618.309

Baronchelli, F., Zucchella, C., Serrao, M., Intiso, D., & Bartolo, M. (2021). The effect of robotic assisted gait training with Lokomat® on balance control after stroke: Systematic review and meta-analysis. *Frontiers in Neurology*, *12*, 661815. https://doi.org/10.3389/fneur.2021.661815

Bessler, J., Prange-Lasonder, G. B., Schulte, R. V., Schaake, L., Prinsen, E. C., & Buurke, J. H. (2020). Occurrence and type of adverse events during the use of stationary gait

robots-A systematic literature review. *Frontiers in Robotics and AI*, *7*, 557606. https://doi.org/10.3389/frobt.2020.557606

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

Bowman, T., Gervasoni, E., Amico, A. P., Antenucci, R., Benanti, P., Boldrini, P., Bonaiuti, D., Burini, A., Castelli, E., Draicchio, F., Falabella, V., Galeri, S., Gimigliano, F., Grigioni, M,. Mazzon, S., Mazzoleni, S., Mestanza Mattos, F. G., Molteni, F., Morone, G., … "Cicerone" Italian Consensus Group for Robotic Rehabilitation. (2021). What is the impact of robotic rehabilitation on balance and gait outcomes in people with multiple sclerosis? A systematic review of randomized control trials. *European Journal of Physical and Rehabilitation Medicine*, *57*(2), 246-53. https://doi.org/10.23736/S1973-9087.21.06692-2

Calabrò, R. S., Sorrentino, G., Cassio, A., Mazzoli, D., Andrenelli, E., Bizzarini, E., Campanini, I., Carmignano, S. M., Cerulli, S., Chisari, C., Colombo, V., Dalise, S., Fundarò, C., Gazzotti, V., Mazzoleni, D., Mazzucchelli, M., Melegari, C., Merlo, A., Stampacchia, G., … Italian Consensus Conference on Robotics in Neurorehabilitation (CICERONE). (2021a). Robotic-assisted gait rehabilitation following stroke: a systematic review of current guidelines and practical clinical recommendations. *European Journal of Physical and Rehabilitation Medicine*, *57*(3), 460–471. https://doi.org/10.23736/S1973-9087.21.06887-8

Calabrò, R. S., Cassio, A., Mazzoli, D., Andrenelli, E., Bizzarini, E., Campanini, I., Carmignano, S. M., Cerulli, S., Chisari, C., Colombo, V., Dalise, S., Fundarò, C., Gazzotti, V., Mazzoleni, D., Mazzucchelli, M., Melegari, C., Merlo, A., Stampacchia, G., Boldrini, P., … Italian Consensus Conference on Robotics in Neurorehabilitation (CICERONE). (2021b). What does evidence tell us about the use of gait robotic devices in patients with multiple sclerosis? A comprehensive systematic review on functional outcomes and clinical recommendations. *European Journal of Physical and Rehabilitation Medicine*, *57*(5), 841–849. https://doi.org/10.23736/S1973-9087.21.06915-X

Calafiore, D., Negrini, F., Tottoli, N., Ferraro, F., Ozyemisci-Taskiran, O., & de Sire, A. (2022). Efficacy of robotic exoskeleton for gait rehabilitation in patients with subacute stroke : a systematic review. *European Journal of Physical and Rehabilitation Medicine*, *58*(1), 1–8. https://doi.org/10.23736/S1973-9087.21.06846-5

Carvalho, I., Pinto, S. M., Chagas, D. das V., Praxedes dos Santos, J. L., de Sousa Oliveira, T., & Batista, L. A. (2017). Robotic gait training for individuals with cerebral palsy: A systematic review and meta-analysis. *Archives of Physical Medicine and Rehabilitation*, *98*(11), 2332–2344. https://doi.org/10.1016/j.apmr.2017.06.018

Conner, B. C., Remec, N. M., & Lerner, Z. F. (2022). Is robotic gait training effective for individuals with cerebral palsy? A systematic review and meta-analysis of randomized controlled trials. *Clinical Rehabilitation*, *36*(7), 873–882. https://doi.org/10.1177/02692155221087084

Cumplido, C., Delgado, E., Ramos, J., Puyuelo, G., Garcés, E., Destarac, M. A., Plaza, A., Hernández, M., Gutiérrez, A., & García, E. (2021). Gait-assisted exoskeletons for children with cerebral palsy or spinal muscular atrophy: A systematic review. *NeuroRehabilitation*, *49*(3), 333–348. https://doi.org/10.3233/NRE-210135

Fang, C.-Y., Tsai, J.-L., Li, G.-S., Lien, A. S.-Y., & Chang, Y.-J. (2020). Effects of robot-assisted gait training in individuals with spinal cord injury: A meta-analysis. *BioMed Research International*, *2020*, 2102785. https://doi.org/10.1155/2020/2102785

Hayes, S. C., James Wilcox, C. R., Forbes White, H. S., & Vanicek, N. (2018). The effects of robot assisted gait training on temporal-spatial characteristics of people with spinal cord injuries: A systematic review. *The Journal of Spinal Cord Medicine*, *41*(5), 529–543. https://doi.org/10.1080/10790268.2018.1426236

Hornby, T. G., Reisman, D. S., Ward, I. G., Scheets, P. L., Miller, A., Haddad, D., Fox, E. J., Fritz, N. E., Hawkins, K., Henderson, C. E., Hendron, K. L., Holleran, C. L., Lynskey, J. E., Walter, A., & and the Locomotor CPG Appraisal Team. (2020). Clinical practice guideline to improve locomotor function following chronic stroke, incomplete spinal cord injury, and brain injury. *Journal of Neurologic Physical Therapy: JNPT*, *44*(1), 49–100. https://doi.org/10.1097/NPT.0000000000000303

Llamas-Ramos, R., Sánchez-González, J. L., & Llamas-Ramos, I. (2022). Robotic systems for the physiotherapy treatment of children with cerebral palsy: A systematic review. *International Journal of Environmental Research and Public Health*, *19*(9). https://doi.org/10.3390/ijerph19095116

Legal notes. (2016, October 4). Hocoma. https://www.hocoma.com/legal-notes/

Lorusso, M., Tramontano, M., Casciello, M., Pece, A., Smania, N., Morone, G., & Tamburella, F. (2022). Efficacy of overground robotic gait training on balance in stroke survivors: A systematic review and meta-analysis. *Brain Sciences*, *12*(6), 713. https://doi.org/10.3390/brainsci12060713

Nam, K. Y., Kim, H. J., Kwon, B. S., Park, J.-W., Lee, H. J., & Yoo, A. (2017). Robot-assisted gait training (Lokomat) improves walking function and activity in people with spinal cord injury: a systematic review. *Journal of Neuroengineering and Rehabilitation*, *14*(1). https://doi.org/10.1186/s12984-017-0232-3

Nedergård, H., Arumugam, A., Sandlund, M., Brråndal, A., & Häger, C. K. (2021). Effect of robotic-assisted gait training on objective biomechanical measures of gait in persons post-stroke: a systematic review and meta-analysis. *Journal of Neuroengineering and Rehabilitation*, *18*(1), 64. https://doi.org/10.1186/s12984-021-00857-9

Mehrholz, J., Thomas, S., Kugler, J., Pohl, M., & Elsner, B. (2020). Electromechanical-assisted training for walking after stroke. *Cochrane Database of Systematic Reviews*, *10*(10), CD006185. https://doi.org/10.1002/14651858.CD006185.pub5

Mehrholz, J., Pohl, M., Kugler, J., & Elsner, B. (2021). Electromechanical-assisted training for walking after stroke: Update of the evidence. *Stroke; a Journal of Cerebral Circulation*, *52*(5), e153–e154. https://doi.org/10.1161/STROKEAHA.120.033755

Olmos-Gómez, R., Gómez-Conesa, A., Calvo-Muñoz, I., & López-López, J. A. (2021). Effects of robotic-assisted gait training in children and adolescents with cerebral palsy: A network meta-analysis. *Journal of Clinical Medicine*, *10*(21), 4908. https://doi.org/10.3390/jcm10214908

Sattelmayer, M., Chevalley, O., Steuri, R., & Hilfiker, R. (2019). Over-ground walking or robot-assisted gait training in people with multiple sclerosis: does the effect depend on baseline walking speed and disease related disabilities? A systematic review and meta-regression. *BMC Neurology*, *19*(1), 93. https://doi.org/10.1186/s12883-019-1321-7

Volpini, M., Aquino, M., Holanda, A. C., Emygdio, E., & Polese, J. (2022). Clinical effects of assisted robotic gait training in walking distance, speed, and functionality are maintained over the long term in individuals with cerebral palsy: a systematic review and meta-analysis. *Disability and Rehabilitation*, *44*(19), 5418–5428. https://doi.org/10.1080/09638288.2021.1942242

Yeh, S.-W., Lin, L.-F., Tam, K.-W., Tsai, C.-P., Hong, C.-H., & Kuan, Y.-C. (2020). Efficacy of robot-assisted gait training in multiple sclerosis: A systematic review and meta-analysis. *Multiple Sclerosis and Related Disorders*, *41*(102034), 102034. https://doi.org/10.1016/j.msard.2020.102034

Zhang, L., Lin, F., Sun, L., & Chen, C. (2022). Comparison of efficacy of Lokomat and wearable exoskeleton-assisted gait training in people with spinal cord injury: A systematic review and network meta-analysis. *Frontiers in Neurology*, *13*, 772660. https://doi.org/10.3389/fneur.2022.772660

Research Request – Availability of hydrotherapy, swimming pool, outside exercise programs and social engagement activities

Brief	Please provide information regarding availability in participants community of the following options (within a 20km range): • Hydrotherapy • Pools • Outside Exercise Programs • Social Engagement Activities
Date	13/08/2020
Requester	Naomi s22(1)(a)(ii) - irrele (Senior Technical Advisor)
Researcher	Jane s22(1)(a)(ii) - irreleva (Research Team Leader)

Contents

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

The distance between the service provider and the participant's home is provided. Only those found within a 20km radius have been listed.

Hydrotherapy

1. Noosa Hospital (4.2km)

111 Goodchap St, Noosaville, QLD, 4566

0754559224

2. Noosa Sports & Spinal Physiotherapy Centre (4.5km)

Suite 202, 90 Goodchap Street, Noosaville, QLD, 4566

07 5449 0024

https://www.noosasportsphysio.com.au/services/

Pools

1. Noosa Aquatic Centre (11.4km)

All pools are disability accessible

- 50m pool (10 lanes)
- 25m pool (8 lanes)
- Leisure pools (heated, shaded and beach entry)

Social Engagement

1. Sunshine Butterflies (6.5km)
   485 McKinnon Drive, Cooroibah, QLD, 4565

   https://www.sunshinebutterflies.com.au/programs-and-activities

Educational and Recreational Programs delivered by Sunshine Butterflies

- **Chippies Corner:** For the wood-working enthusiasts to design, create and construct.
- **Assistance with daily living:**
  - Transport: teaching about being independent, confident and safe on public transport.
  - Personal Grooming: assistance with developing a healthy lifestyle, a positive outlook and teach you about your health needs such as hygiene, diet and fitness.
  - Capacity and Life Skill Training: support and development of individual's skills from budgeting through to meal preparation.

- Create Your Own Business: a model developed to create self-employment and purpose for individuals who may have difficulties finding work within their community.
- Community Volunteering: if you're looking for support to help you give back to your community in a volunteering role, we are able to help you achieve your goal and get involved

- **Community connect**: Enjoy a variety of outings whether it be fishing or a BBQ at the river, fun at the park, visiting local attractions and exploring our national parks.
- **Kiss my art**: Trained artists with specialist skills guide the classes and coordinate and facilitate workshops and projects to encourage a collaboration between artists with and without disability. Work alongside each other in a stimulating and supportive environment to develop social skills and extend friendships.
- **Farmyard cooking school**: program covers all aspects of food preparation, including shopping for ingredients, menu planning, learning how to follow recipes, safe food handling, correct measurement reading, cooking times and table setting. It is also a great way to socialise with friends, working together to prepare a healthy and nutritious lunch to share together.

Exercise (including outdoor)

1. Sunshine Butterflies (6.5km)

- **Fitness, Sport and Recreation:** if you're into keeping fit and enjoy the gym, hiking, bike riding, tennis and just general fitness, Sunshine Butterflies can offer you a support buddy so you can participate in more of the things you want to do.
- **Fitability:** modified sports, games and fitness program giving participants an opportunity to partake in activities at their own pace and get fit in a fun and supportive environment.
- **Personal training & Wellbeing:** programs are flexible to member's needs and abilities. Sunshine Butterflies staff can assist you with your personal training and health needs or accompany you to your fitness sessions

2. Age Well For Life Exercise Physiology
   Located in Maroochydore – will travel across Sunshine Coast

   https://agewellforlife.com.au/

   - Provides in home physical health and well-being services to people with a permanent disability.

3. Full Circle Wellness (4.7km)

   10 Wallace Drive, Noosaville, QLD, 4566

   https://www.fullcirclewellness.com.au/noosa-and-tewantin

- Full Circle Wellness offers Exercise Physiology classes and mobile services to clients in the Noosa District. Senior Exercise Physiologist, Tristan Hall, is available for home visits in and around the Noosa area.
- Specialising in aged care and rehabilitation we are also an NDIS provider dedicated to helping improve our patients quality of life through education and individualised exercise programs based on your unique circumstances.

4. Fitness Enhancement Personal Trainers
https://fitnessenhancement.com/services/personal-trainer/sunshine-coast/noosa-heads/

- There are various personal trainers throughout the Noosa region who specialise in personal and small group training. This can be provided indoors or outdoors, and even at the participants house. Fitness Enhancement Personal Trainers specialise in older adult's fitness and are NDIS registered.

Research Request – Computer & Fitness Price Comparisons

Brief	Find some comparative prices for the following equipment: 1. For the computer type equipment, they need to be compatible with social media, and able to manage: • Full Microsoft excel suite with data pack add on – need to hold up to 200 excel spreadsheets • Visual software to create data visualisations 2. Please look at laptops, note books and tablets (they need to be portable). Please source smart keyboards (prices) as well as a standard keyboard. 3. Please look at prices for stationary bikes. 4. Please source prices for: medicine ball – different weights, exercise bands, yoga mat, adjustable chin up bar, jump rope.
Date	29/07/19 (Prices also as of this date)
Prepared for	Shannon s22(1)(a)(ii) - irre and Susan s22(1)(a)(ii) - irrele
Prepared by	Craig s22(1)(a)(ii) - I

Items highlighted in green indicate the item requested by the participant

Contents

Stationary/Exercise Bike (Upright)

(Information is based on the basic lowest cost item and will usually be the "bottom of the range" from the retailer. Features of the item will be same or similar unless specified in notes).

Retailer	Product Name	Cost	Notes	Link to Product
K Mart	Magnetic Exercise Bike	94.00		Link>
Target	Fila Magnetic Exercise Bike	120.00		Link>
Big W	York Active 100 Exercise Bike	149.00		Link>
Harvey Norman	Powertrain Air Resistance Spin Bike	187.00	Online purchase only	Link>
Rebel	Proform 70CSX Exercise Bike	299.99		Link>
CrazySales	Lifespan SP-310 Spin Bike	319.96	Online purchase only	Link>
CrazySales	Lifespan SP-460 Spin Bike	409.96	Online purchase only	Link>
CrazySales	Lifespan sp 550 spin bike	599.96	Online purchase only	Link>
Ivanhoe Cycles	Lifespan SP-950 Spin Bike	999.90		Link>

Medicine Ball

Retailer	Product Name	Cost	Notes	Link to Product
K Mart	3kg Medicine Ball	20.00	3kg	Link>
K Mart	5kg Medicine Ball	24.00	5kg	Link>
Harvey Norman	Lifespan Fitness 2kg Medicine Ball	28.00	2 kg (Online purchase only)	Link>
Rebel	Celsius 2kg Medicine Ball	29.00	2kg	Link>
Harvey Norman	Lifespan Fitness 4kg Medicine Ball	35.00	4kg (Online purchase only)	Link>
Rebel	Celsius 3kg Medicine Ball	39.99	3kg	Link>
Harvey Norman	Lifespan Fitness 6kg Medicine Ball	45.00	6kg (Online purchase only)	Link>
Rebel	Celsius 4kg Medicine Ball	49.99	4kg	Link>
Rebel	Celsius 6kg Medicine Ball	69.99	6kg	Link>

Yoga Mat

Retailer	Product Name	Cost	Notes	Link to Product
K Mart	Red Fitness Mat	7.50		Link>
K Mart	Yoga Mat	8.00		Link>
Big W	Circuit Yoga Mat	8.00		Link>
Target	3mm Yoga Mat	9.00		Link>
Big W	Circuit 6mm Yoga Mat	10.00		Link>
Big W	MB Active Yoga & Fitness Mat	15.00		Link>
Rebel	Celsius 4mm Yoga Mat	19.99		Link>
K Mart	Non-Slip Yoga Mat	20.00		Link>
K Mart	Fitness Mat	22.00	Thick with carry handle	Link>

Jump Rope

Retailer	Product Name	Cost	Notes	Link to Product
K Mart	Light Up Jump Rope	3.00		Link>
K Mart	Weighted Jump Rope	4.00		Link>
Big W	Circuit Jump Rope with Meter	10.00	With count meter	Link>
Big W	Circuit Weighted Jump Rope	12.00	Weighted	Link>
Rebel	PTP Elite Jump Rope	24.99		Link>
Rebel	PTP Power Weighted Jump Rope	29.99		Link>

Exercise Bands

Retailer	Product Name	Cost	Notes	Link to Product
Big W	Circuit Resistance Band	5.00		Link>
K Mart	Resistance Band	8.00		Link>
K Mart	2 Band Resistance Trainer	8.00		Link>
K Mart	Medium Resistance Muscle Band	10.00		Link>
Big W	Circuit Medium Resistance Band	10.00		Link>
K Mart	Heavy Resistance Muscle Band	16.00		Link>

Research Request – Epilepsy & Seizure Monitoring Systems

Brief	What are the types of AT seizure monitoring devices available? Is there the evidence of efficacy and seizure monitoring AT for epilepsy and seizure conditions, e.g. seizure mats, personally worn monitors and video/audio monitoring? If possible, please seek to identify if findings demonstrate any difference in which items are affective/ineffective or designed for children vs adults in their application. When we would choose a specific type of AT (likely to be determined by their treating physician)? Additional information regarding incidence of seizures in children vs adults – i.e. – if TAT are receiving requests to fund high cost AT monitoring for a child, what seizure conditions are likely to decrease or cease as child ages, and therefore unlikely to represent value for money? What are common known triggers for seizures? What are common seizure conditions? This may help advice with regard to other options that could be considered rather than monitoring when seizure occurs.
Date	December 2019
Prepared for	Julie [redacted] (Assistant Director (TAT)
Prepared by	Craig [redacted] (Tactical Research Advisor - TAT/AAT) Aanika [redacted] (Research Team Leader - TAT)
Cleared by	

Contents

Please note:

The research and literature reviews collated by our TAT Research Team are not to be shared external to the Branch. These are for internal TAT 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.

Related TAB Research

NED20/191674 : RES HWB/AT Thermoregulation Dysfunction and Seizures

Seizure Monitoring Systems/Devices

A seizure alert device is a monitoring system that can detect when a person may be having a seizure and notify someone who can respond. Devices can be used by people of any age. Some systems also record and store seizure data that can be shared with your physician. Seizure alert devices do not prevent, diagnose or treat seizures or epilepsy. [1]

"Currently, seizure tracking relies on subjective patient and family recall and may be influenced by the capacity to identify seizures, the level of awareness during the event, and the ability to remember details afterward... Seizure detection devices provide more accurate seizure quantification, allowing clinicians to tailor treatment more objectively. In addition, seizure prediction devices may alert when an upcoming seizure is going to occur and may enhance patient and family confidence and improving quality of life". [2]

General commonly known conditions and triggers of seizures

A seizure occurs when a burst of electrical impulses in the brain escape their normal limits. They spread to neighbouring areas and create an uncontrolled storm of electrical activity. The electrical impulses can be transmitted to the muscles, causing twitches or convulsions. [3]

A seizure can cause changes in your behaviour, movements or feelings, and in levels of consciousness. If you have two or more seizures or a tendency to have recurrent seizures, you have epilepsy. [4]

The cause for epilepsy in only understood in a minority of the cases. Typically, the known causes of seizure involve some injury to the brain. Some of the main causes of epilepsy include:

- Low oxygen during birth
- Head injuries that occur during birth or from accidents during youth or adulthood
- Brain tumours
- Genetic conditions that result in brain injury, such as tuberous sclerosis
- Infections such as meningitis or encephalitis
- Stroke or any other type of damage to the brain
- Abnormal levels of substances such as sodium or blood sugar

---

[1] Epilepsy Foundation of America, Considering a seizure alert device, 2018 [online brochure], https://www.epilepsy.com/sites/core/files/atoms/files/DAS100_Seizure_Alert_Devices_09-2018_FINAL2.pdf, (accessed 19 August 2019).

[2] A. Ulate-Campos et al. "Automated seizure detection systems and their effectiveness for each type of seizure", Seizure
Volume 40, August 2016, Pages 88-101.
https://www.sciencedirect.com/science/article/pii/S1059131116300711

[3] WebMD, "Common Epilepsy Causes and Seizure Triggers", [website], 2019, https://www.webmd.com/epilepsy/guide/epilepsy-causes, (accessed 9 December 2019)

[4] Mayo Clinic, "Seizures", [website], 2019, https://www.mayoclinic.org/diseases-conditions/seizure/symptoms-causes/syc-20365711, (accessed 9 December 2019)

In up to 70% of all case of epilepsy in adults and children, no cause can be discovered. [5]

Other common triggers:

- Forgetting/unable to take medication (e.g. vomiting)
- Sleep deprivation / fatigue
- Emotional stress
- Alcohol or drugs
- Extreme temperatures, particularly heat or fever
- Flashing lights (e.g. from video games, strobe lights), this is an uncommon trigger and only applies to a small proportion of people with epilepsy, typically those with a genetic epilepsy.[6]

Types of seizures

The following seizure types are summarized below:

- Epileptic Seizures
- Non-epileptic Seizures
- Febrile Seizures
- Infantile Spasms (West Syndrome)
- Pyridoxine-dependent seizures

Epileptic Seizures

Physicians look at the following three things when classifying an epileptic seizure:

1. Where in the brain the seizure starts (e.g. the onset)
2. If the person is aware or not during the seizure
3. Whether the seizure involves movement.

Epileptic seizures can be divided into three major groups.

Below is a table indicating the types of epileptic seizures,[7] together with the condition of the seizure (what the patient experiences and how they may present), and what might trigger the type of seizure.

In 2017, the International League Against Epilepsy revised its classification of seizures to make diagnosing and classifying seizures more accurate and easier. The classifications are used below.

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
Focal Onset Formerly known as	**Focal aware**	The person is fully aware of what's happening around them but may not	The cause is often unknown. [8]

[5] WebMD, "Common Epilepsy Causes and Seizure Triggers", [website], 2019, https://www.webmd.com/epilepsy/guide/epilepsy-causes, (accessed 9 December 2019)
[6] Queensland Paediatric Epilepsy Network, New Diagnosis of Epilepsy Fact Sheet", https://www.childrens.health.qld.gov.au/wp-content/uploads/PDF/qpen-new-diagnosis-booklet.pdf
[7] Epilepsy Action Australia, Seizure Types , [website], 2019, https://www.epilepsy.org.au/about-epilepsy/understanding-epilepsy/seizure-types-and-classification, (accessed 25 November 2019)
[8] Cedars Sinai, "Simple Partial Seizures", [website], 2019, https://www.cedars-sinai.edu/Patients/Health-Conditions/Simple-Partial-Seizures.aspx?_ga=2.63216303.1656684614.1575939601-329177124.1575939601, (accessed 9 December 2019)

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
partial seizures, where the seizure starts in just one small region of the brain. It may spread to other areas of the brain.	Formerly known as simple partial seizures	be able to talk or respond. They are usually brief, and are often called a warning or 'aura' (that a more significant seizure may develop) but are actually part of the seizure.	
	Focal impaired awareness Formerly known as a complex partial seizure.	Awareness is affected and the person may appear confused, vague or disorientated.	Usually start in one area or group of brain cells, most often in the temporal lobe or frontal lobe of the brain. They can also start in other areas too. The seizures starting in the frontal lobe tend to be shorter than the ones from the temporal lobe. They may be more likely in people who have had a head injury, brain infection, stroke, or brain tumour. Often though, the cause is unknown. [9]
Generalised Onset Can be classified by movement	**Absence**	A sudden lapse in awareness and responsiveness that look like brief staring spells or daydreaming	Like other kinds of seizures, absence seizures are caused by abnormal activity in a person's brain. Doctors often don't know why this happens. Most absence seizures are less than 15 seconds long. It's rare for an absence seizure to last longer than 15 seconds. They can happen suddenly without any warning signs.[10]
	Tonic-Clonic	The body stiffens (the tonic phase) and then the limbs begin to jerk rhythmically (the clonic phase)	"Sometimes caused by underlying health problems, such as: Injury or infection: Traumatic head injuries, Infections, such as encephalitis or meningitis, or a history of such infections, Injury due to a previous lack of oxygen, Stroke Congenital or developmental abnormalities: Blood vessel malformations in the brain, Genetic syndromes, Brain tumors. Metabolic disturbances: Very low blood levels of glucose, sodium, calcium or magnesium, Withdrawal syndromes, Using or withdrawing from drugs, including alcohol. [11]
	Myoclonic	Sudden single jerks of a muscle or a group of muscles that may last no more than a second or two.	Myoclonus may develop in response to infection, head or spinal cord injury, stroke, brain tumours, kidney or liver failure, lipid storage disease, chemical or drug poisoning, or other disorders. Prolonged oxygen deprivation to the brain, called hypoxia, may result in posthypoxic myoclonus. Myoclonus can occur by itself, but most often it is one of several symptoms associated with a wide variety of nervous system disorders. For example, myoclonic jerking may develop in

[9] Epilepsy Foundation, "Focal Onset Impaired Awareness Seizures (complex partial seizures)", [website], 2019, https://www.epilepsy.com/learn/types-seizures/focal-onset-impaired-awareness-seizures-aka-complex-partial-seizures, (accessed 9 December 2019)

[10] John Hopkins Medicine, "Absence Seizures", [website], 2019, https://www.hopkinsmedicine.org/health/conditions-and-diseases/epilepsy/absence-seizures, (accessed 9 December 2019)

[11] Mayo Clinic, "Grand mal seizure", [website], 2019, https://www.mayoclinic.org/diseases-conditions/grand-mal-seizure/symptoms-causes/syc-20363458, (accessed 28 November 2019)

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
			patients with multiple sclerosis, Parkinson's disease, Alzheimer's disease, or Creutzfeldt-Jakob disease. Myoclonic jerks commonly occur in persons with epilepsy, a disorder in which the electrical activity in the brain becomes disordered leading to seizures. [12]
	Tonic	Can occur when a person is asleep or awake and involves a brief stiffening of the body arms or legs. The person will suddenly fall if standing or sitting. They are more common in people who have Lennox-Gastaut syndrome or other syndromes with mixed seizure types. When a tonic seizure ends, the person may or may not be sleepy or confused. [13]	Originates in both halves (hemispheres) of the brain simultaneously. A tonic or clonic seizure can also begin in one area of the brain (called a partial or focal seizure), affecting only one part of the body such as an arm or a leg. [14]
	Atonic	Brief seizures that cause a sudden loss muscle tone and the person often falls to the ground or will have a sudden head nod if sitting.	The cause of atonic seizures is often unknown. Some patients may be more likely to have seizures because of changes in their genes. [15]
	Clonic	Although uncommon they cause jerking in various parts of the body.	Originates in both halves (hemispheres) of the brain simultaneously. A tonic or clonic seizure can also begin in one area of the brain (called a partial or focal seizure), affecting only one part of the body such as an arm or a leg. [16]
Unknown Onset	**N/A**	The seizure cannot be diagnosed as either focal or generalised onset. Sometimes this classification is temporary and as more information becomes available over time or through further testing, the type of	Unknown

[12] National Institute of Neurological Disorders and Stroke, "Grand mal seizure", [website], 2019, https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Myoclonus-Fact-Sheet, (accessed 28 November 2019)
[13] Epilepsy Foundation, "Tonic Seizures", [website], 2019, https://www.epilepsy.com/learn/types-seizures/tonic-seizures, (accessed 9 December 2019)
[14] John Hopkins Medicine, "Tonic and Clonic Seizures", [website], 2019, https://www.hopkinsmedicine.org/health/conditions-and-diseases/epilepsy/tonic-and-clonic-seizures, (accessed 9 December 2019)
[15] Cedars Sinai, "Atonic Seizures", [website], 2019, https://www.cedars-sinai.edu/Patients/Health-Conditions/Atonic-Seizures.aspx?_ga=2.105746691.1656684614.1575939601-329177124.1575939601, (accessed 9 December 2019)
[16] John Hopkins Medicine, "Tonic and Clonic Seizures", [website], 2019, https://www.hopkinsmedicine.org/health/conditions-and-diseases/epilepsy/tonic-and-clonic-seizures, (accessed 9 December 2019)

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
		seizure may be changed to a generalised or focal onset seizure.	

Non epileptic Seizures

Non epileptic seizures are known as psychogenic non-epileptic seizures (PNES). PNES have been labelled many names. Some common terms used are:

- Pseudo seizures
- Dissociative seizures
- Non epileptic events
- Non epileptic attack disorder (NEAD)
- Functional neurological disorder (FND)
- Conversion disorder (psychiatric diagnosis) [17]

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
Non Epileptic (Psychogenic non-epileptic seizures (PNES)	N/A	Sudden, involuntary changes in behaviour, sensation, motor activity, cognitive processing (can include change in level of consciousness) or autonomic function (e.giuiu. blood pressure, heart rate) linked to psychological or social distress. These events look like epileptic seizures, but are not caused by abnormal electrical discharges in the brain.	Emotional or psychological cause rather than a physiological one and can be seen in people with or without epilepsy. PNES function as a coping mechanism. Research indicates that people with these events are more likely to use poor coping strategies to handle stress.

Febrile Seizures

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
Febrile Seizure	N/A	Febrile seizures are seizures or convulsions that occur in young children and are triggered by fever. Young children between the ages of about 6 months and 5 years old are the most likely to experience febrile seizures; this risk peaks during the second year of life...The vast majority of febrile seizures are convulsions. Most often during a febrile seizure, a child will lose consciousness and both arms and legs will shake uncontrollably. Less common symptoms include eye rolling, rigid (stiff) limbs, or twitching on only one side	It has been established that febrile seizures and its extended syndromes like generalized epilepsy with febrile seizures (FS) plus (GEFS+) and Dravets syndrome have been associated with mutations especially in *SCN1A* and *GABRG2* genes. In patients, the onset of FS is likely due to the combined effect of temperature and inflammation in genetically vulnerable individuals because fever is often associated with infection. . . We demonstrated age-dependent dysregulated temperature control and that temperature elevation produced myoclonic jerks, generalized tonic clonic seizures (GTCSs) and heightened anxiety-like symptoms in

[17] Epilepsy Action Australia, "Psychogenic non-epileptic seizures", [website], 2017 https://www.epilepsy.org.au/epilepsy-trainer-news-feature-psychogenic-non-epileptic-seizures, (accessed 26 November 2019).

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
		or a portion of the body, such as an arm or a leg. Sometimes during a febrile seizure, a child may lose consciousness but will not noticeably shake or move....Most febrile seizures last only a few minutes and are accompanied by a fever above 101°F (38.3°C). [18]	*Gabrg2*$^{+/Q390X}$ mice. The study indicated that regardless of other inflammatory factors, brief heat alone increased brain excitability and induced multiple types of seizures in *Gabrg2*$^{+/Q390X}$ mice, suggesting that mutations like *GABRG2 (Q390X)* may alter brain thermal regulation and precipitate seizures during temperature elevations. [19]

Infantile Spasms (West Syndrome)

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
Infantile Spasms (also referred to as "West Syndrome")	N/A	The spasms consist of a sudden stiffening. Often the arms flung out as the knees are pulled up and the body bends forward ("jackknife seizures"). Less often, the head can be thrown back as the body and legs stiffen in a straight-out position. Movements can also be more subtle and limited to the neck or other body parts. Infants can cry during or after the seizure. Each seizure lasts only a second or two but they usually occur close together in a series. Sometimes the spasms are mistaken for colic, but the cramps of colic do not occur in a series. [20] Some infants may be at risk of slow development because of the condition already affecting the brain before the onset of spasms. But many parents notice that their infant behaves differently when the spasms start. Their child may lose interest in their surroundings, taking less notice of their parents.	Any condition that damages the brain can cause infantile spasms, also called West syndrome. Some of the causes happen before a baby is born (prenatal) and some happen after birth (postnatal). The most common cause is an inherited condition called tuberous sclerosis complex. It makes noncancerous tumours grow in different body parts, like your baby's brain, skin, kidneys, or other organs. If your baby has them, you might notice colorless bumps on her skin. Other causes of West syndrome include: Brain injury, Problems with the way the brain formed, Changes in brain structure, Lack of oxygen to the brain, Brain infections, Lesions on the brain, Bleeding inside the skull, Inflammation in the brain (encephalitis), Metabolism disorders, Vitamin B deficiency. [22]

[18] National Institute of Neurological Disorders and Stroke, "Febrile Seizures Fact Sheet", [website], 2019, https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Febrile-Seizures-Fact-Sheet, (accessed 28 November 2019)

[19] Warner, TA et al., 'Heat induced temperature dysregulation and seizures in Dravet Syndrome/GEFS+ Gabrg2+/Q390X mice', Epilepsy research, vol. 134, 2017, pp.1-8, https://www.sciencedirect.com/science/article/abs/pii/S0920121117302620, accessed 10 October 2019.

[20] Epilepsy Foundation, "Infantile Spasms (West's Syndrome) and Tuberous Sclerosis Complex", [website], 2019, https://www.epilepsy.com/learn/types-epilepsy-syndromes/infantile-spasms-wests-syndrome-and-tuberous-sclerosis-complex, (accessed 9 December 2019)

[22] WebMD, "What Causes Infantile Spasms?", [website], 2019, https://www.webmd.com/children/west-syndrome-causes, (accessed 9 December 2019)

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
		Some infants become irritable or drowsy. Parents often wonder what is happening because of this change in personality. But not all infants show this change. It used to be thought that infants had to suffer from this and from delayed development before doctors should use the name West syndrome. But it is not necessary for the infants to have abnormal development before calling the condition either infantile spasms or West syndrome. That is because some infants with infantile spasms will continue to have normal development. [21]	

Pyridoxine-dependent seizures

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
Pyridoxine-dependent seizures (Other Names: Pyridoxine dependency; Pyridoxine dependency with seizures; Vitamin B6-dependent seizures)	N/A	A condition that involves seizures beginning in infancy or, in some cases, before birth. Those affected typically experience prolonged seizures lasting several minutes (status epilepticus). These seizures involve muscle rigidity, convulsions, and loss of consciousness (tonic-clonic seizures). Anticonvulsant drugs, which are usually given to control seizures, are ineffective in people with pyridoxine-dependent epilepsy. Instead, people with this type of seizure are medically treated with large daily doses of pyridoxine (a type of vitamin B6 found in food). Those affected by pyridoxine-dependent epilepsy typically experience prolonged seizures lasting several minutes (status epilepticus). These seizures involve muscle rigidity, convulsions, and loss of consciousness (tonic-clonic	Mutations in the ALDH7A1 gene cause pyridoxine-dependent epilepsy. This condition is inherited in an autosomal recessive pattern, which means both copies of the gene in each cell have mutations. The parents of an individual with an autosomal recessive condition each carry one copy of the mutated gene, but they typically do not show signs and symptoms of the condition. [24]

[21] J. Osborne et al., "Infantile Spasms and West Syndrome: An explanatory booklet for parents and for professionals", 2006, https://www.rch.org.au/uploadedFiles/Main/Content/neurology/20060215_InfantileSpasms_handout.pdf
[24] ibid

Seizure Type	Seizure Sub-Type	Conditions	Triggers/Causes
		seizures). Additional features of pyridoxine-dependent epilepsy include low body temperature (hypothermia), poor muscle tone (dystonia) soon after birth, and irritability before a seizure episode. In rare instances, children with this condition do not have seizures until they are 1 to 3 years old. [23]	

Other Resources . . .

- Epilepsy Action Australia, Fact Sheet: Seizure Classification
- Epilepsy Action Australia, International League Against Epilepsy: Seizure Classification 2017
- Epilepsy Action Australia, Seizure Classification Chart
- NDIS TAT Research, RES HWB Functional Seizures 2019 0018 ADO283: NED19/157670
- NDIS TAT Research, RES AT Seizure Monitoring Devices 2019/2025 ADO283: NED19/195673
- NDIS TAT Research, RES AT Air conditioning Thermoregulation 2019/0042 ADO283: NED19/222184 (Febrile Seizure)

Evidence of seizure frequency depending on age of patient

There is very little research indicating seizure frequency depending on the age of the patient. Several open source information websites, such as the Australian Medical Association and Consumer Reports reference a substantial 2010 study [25] which suggested that 7 in 10 children diagnosed with epilepsy will grow out of it by the time they are 20. Since that study there appears to be no further substantial research into the subject. None of the open source type literature such as national or state seizure support organisations made mention of this subject, and no other academic research could be sourced.

The above longitudinal study was undertaken by researchers at several hospitals in the Netherlands. The study also concluded that patients can grow out of seizures if they "respond well to early treatment and have fewer seizures in the early years, and if there are no external reason for their epilepsy such as injury or illness".

The study involved 494 children, each of whom had had at least two seizures starting from when they were aged five on average. "The children were followed up for an average of 15 years, so that the final questionnaire about their symptoms was sent out when the subjects were about 20.

[23] Genetic and Rare Diseases Information Centre, "Pyridoxine-dependent epilepsy", [website], 2019, https://rarediseases.info.nih.gov/diseases/9298/pyridoxine-dependent-epilepsy, (accessed 9 November 2019)
[25] A. Geerts et al., "Course and outcome of childhood epilepsy: A 15-year follow-up of the Dutch Study of Epilepsy in Childhood", Epilepsia, Vol 51, No 7, pp. 1189-1197, 2010, https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1528-1167.2010.02546.x

Most of them (71 per cent) were found to be no longer having seizures and not having any for at least five years. Most of these (62 per cent) were no longer taking medication for epilepsy. About 8.5 per cent had epilepsy that was intractable, their seizure-free periods lasting no longer than three months. Eighteen of the 494 children who had begun the study died during the follow-up period, all but one of the deaths being attributed to epilepsy". [26]

The general theme in the limited available literature on the subject is that seizures can reduce as the patient grows older with appropriate treatment, and the appropriate treatment concerns the use of anti-epileptic drugs (AEDs). The Epilepsy Foundation (America) briefly delved into the subject, finding and referencing some research which indicated that:

- About 50 to 60% of patients will be seizure free after using the first seizure medication tried.
- A second seizure medication may help 11 to 20 out of every 100 people become seizure free. Adding more drugs usually doesn't help the chance of seizure control.
- 25 out of every 100 adults will develop uncontrolled epilepsy.
- Others will have continued seizures and side effects, but we don't know if other treatments may help.
- In children with new-onset seizures, 74 out of 100 become seizure free within 2 years
- Uncontrolled epilepsy may be seen in 9 out of 100 children followed for a number of years.[27]

Types of seizure monitoring devices

There are several types of seizure monitoring devices used as personal/home monitoring as opposed to clinical application:

- **Mattresses/mats for beds**
- **Smart watches**
- **Mobile phone applications**
- **Pendants**
- **Bracelet/Anklet**
- **Socks (Babies)**
- **Nappies (Babies)**
- **Oximeter**

Mattresses/mats for beds

A mattress or mat, which is placed under the mattress. Sensor technology detects and distinguishes between normal movements from strong muscle jerking such as tonic-clonic seizures. Also acknowledges the presence and absence of micro-movements caused by a person's breathing and heart beating. Gives notification to a caregiver when the person has the clonic phase of a tonic-clonic seizure, but also when the person leaves the bed.

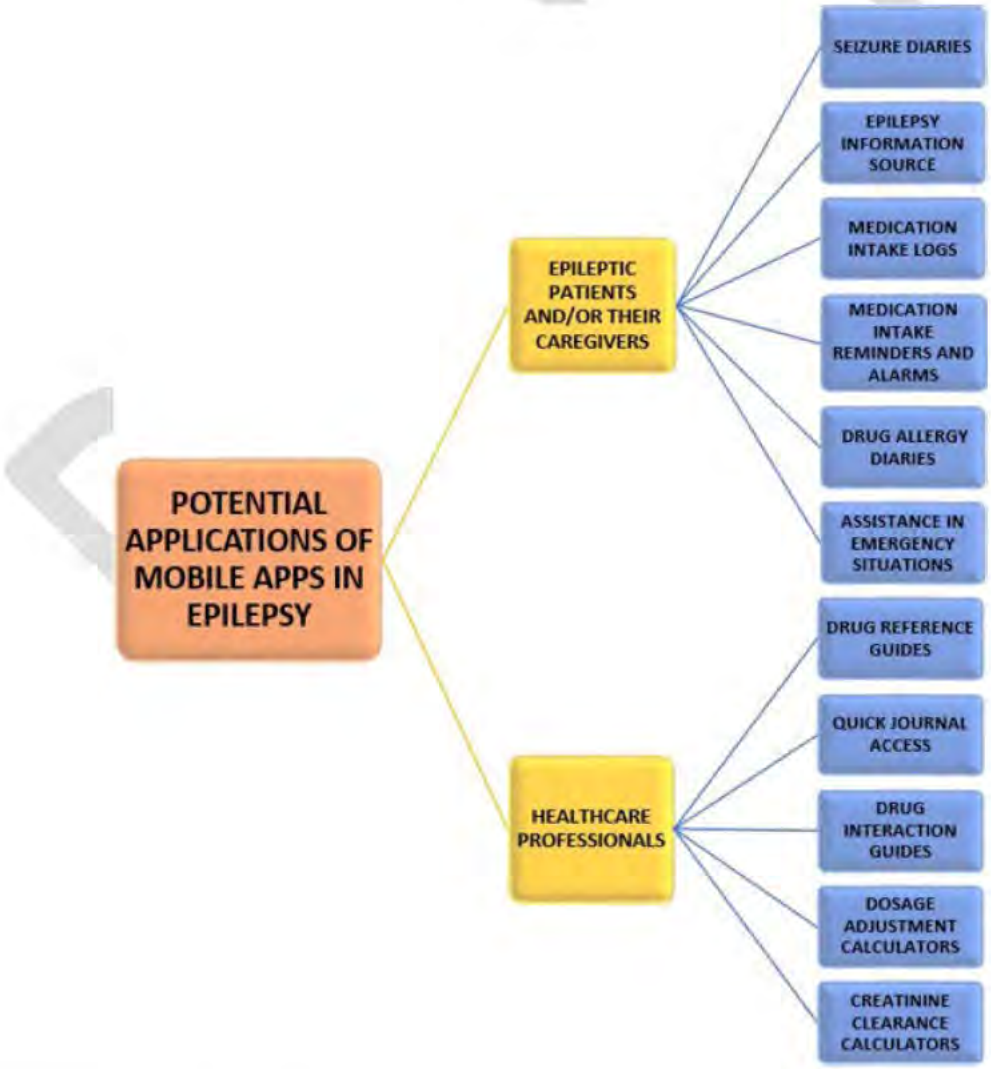
[26] Australian Medical Association, "Epilepsy: 7 out of 10 children grow out of it", [website], 2019, https://ama.com.au/ausmed/epilepsy-7-out-10-children-grow-out-it, (accessed 9 December 2019)
[27] Epilepsy Foundation, "Will I Always Have Seizures?", [website], 2019, https://www.epilepsy.com/learn/about-epilepsy-basics/will-i-always-have-seizures, (accessed 11 December 2019)

Smart watches

Reportedly, monitors movements and instantly alerts family members and caregivers upon the onset of repetitive shaking or abnormal patterns of movement. A smart phone with an application will often accompany the watch.

Mobile phone applications (Apps)

Mobile phone applications have a variety of uses in monitoring seizures, where for example, GPS pendants, monitoring cameras, and baby nappy and sock monitors, will send alerts and data to the mobile device via the application. As well, mobile phone applications are widely used to collect seizure data for seizure management where the patient, carer or health professional inputs the data such as the environment and circumstances in which the seizure occurred, time in hours spent in sleep, medication dosage, frequency of alcohol intake, meal times etc. This information is synced and shared with health professionals to assist in seizure management and diagnosis. Such applications are often referred to as seizure diaries. The diagram below indicates the potential use of applications in epilepsy. [28]



[28] L. Ranganathan et al., "Application of mobile phones in epilepsy care", International Journal of Epilepsy, Vol 2, No 1, pp. 28-37, 2015, https://www.sciencedirect.com/science/article/pii/S2213632015000044

Pendants

Can detect sudden impact of a fall and alert nominated mobile devices and give GPS tracking information to the receiver. Does not detect movement such as shaking or jerking. Other pendants can be simply used as an SOS alert option where the patient presses a button to send an alert.

Bracelet/Anklet

Some pendants can be used as bracelets. A bracelet or anklet device can be worn in conjunction with other monitoring devices. For example the bracelet/Anklet will detect movement when sleeping and send alert and other information to a mobile phone/tablet.

Cameras

Cameras can be used as sleep activity monitors for caregivers and individuals who need to watch for unusual movements at night. During sleep, audio-video information from a remote infrared video camera is sent to a mobile device with an application installed. When an unusual event is detected, it sounds an alarm and records live audio and video from the camera

Socks (Babies)

Sock worn by babies. Tracks heart and oxygen levels and sends real-time data to a smart phone with an application installed.

Nappies (Babies)

Clips on to the babies nappy and monitors breathing movement and sending alerts where breathing movement might stop, to a mobile device with an application installed.

Oximeter

A small clip like device which monitors the oxygen saturation of a patient's blood (as opposed to measuring oxygen saturation directly through a blood sample). Small beams of light pass through the blood in the finger, measuring the amount of oxygen.

Device suitability depending on age of patient

Apart from monitors which attach to a babies nappy and the sock monitor for babies, all other devices appear to be suitable for all age groups. Note: the research would indicate that adults may be more able than children to have knowledge and alert to the onset of some types of seizures.

Seizure Monitoring Products

Below is a selection of seizure monitoring products based on what appears to be the most popular according to prominent community epilepsy organisations.

Product Name	Device Type	Link to Supplier(s)
Embrace 2	Smartwatch	https://www.empatica.com
Enspyre	Smartwatch	https://smart-monitor.com
Apple Watch Series 5	Smartwatch	https://www.apple.com/au/apple-watch-series-5/health
My Medic Watch	Mobile phone/watch App	https://www.mymedicwatch.com

Product Name	Device Type	Link to Supplier(s)
SeizAlarm App	Mobile phone/watch App	http://seizalarm.com
SeizureTracker	Mobile phone App	https://www.seizuretracker.com
Keep Track GPS	Pendant	https://www.keeptrackgps.com.au/products/personal-alarm-telstra-network
Life Minder	Pendent	http://lifeminder.com.au/product/the-life-minder
LiveLife	Pendent	https://livelifealarms.com.au
Sami	Camera	https://www.samialert.com
Pulse Guard	Bracelet/Anklet	https://pulseguard.org
Epi Assist	Mattress/Mat	http://www.epiassist.com.au
Owlet	Socks (Babies)	https://owletcare.com.au
Szuna	Nappies	https://www.snuza.com
Edan	Oximeter	https://amamedicalproducts.com.au/collections/pulse-oximeters/products/edan-h100b-hand-held-pulse-oximeter

Evidence of efficacy of seizure monitoring devices

- **It appears that there is no evidence of efficacy, and no formal selection or prescription guidelines for seizure monitoring devices.**
- **For most of the device types, no reference could be found with regard to efficacy and how a patient may choose a particular device for their particular seizure.**

The majority of literature on the devices is manufacturer marketing and general open source type. Prominent epilepsy organisations, such as Epilepsy Action Australia , and the Epilepsy Foundation in the US, only discuss the types of monitoring devices and what seizure types they might assist to monitor, with links to manufacturer sites for purchase.

Epilepsy Action Australia asserts that *"there are countless products on the market that can help people with seizures or their families feel more comfortable about safety. Please note that monitors, alarms and safety products don't guarantee safety or detection of all seizures, but they can provide peace of mind for some people"*. [29] The American Epilepsy Foundation suggest that *"no alert device has been designed to prevent seizures or possible impact from seizures. There are no devices available that have been proven to prevent* sudden unexpected death in epilepsy (*SUDEP). Yet, since SUDEP most often occurs during sleep, some people with seizures at night may be helped by having a way to let others know if a seizure occurs"*. [30]

No lived experience or opinion regarding referral or prescription from GP's or specialists could be found. There appears to be little research interest in device monitoring from professionals in the field, however there appears to be a rising trend in academic research of monitoring devices including monitoring at a clinical level.

In 2018 the NDIS Technical Advisory Team, conducted a face to face survey of three experts in the field of Neurology and Epileptology. (See Appendix A). The survey evolved from the high rate of

[29] Epilepsy Action Australia, Safety Products and Alarms, [website], 2019, https://www.epilepsy.org.au/e-360-edition-13-safety-products-and-alarms, (accessed 19 August 2019).
[30] Epilepsy Foundation, The Role of Seizure Alerts, [website], 2019, https://www.epilepsy.com/learn/early-death-and-sudep/sudep/role-seizure-alerts, (accessed 19 August 2019).

participants requesting 2:1 seizure monitoring from support workers. The experts were asked if the need for face to face monitoring might be reduced with the use of monitoring or alarm devices, and what monitoring devices would be appropriate for what types of epilepsy?

Only one expert commented that the devices would need to be sensitive: *"This depends upon the type of seizure, the time of day/night and so on. The device needs to be sensitive without too many false alarms. Again, this has to be worked out on an individual basis"*. Another expert commented with regard to the 2:1 support worker support: *"These would be exceptional cases in which there is a severe seizure disorder with severe underlying neurological disability. Superficially, it would seem reasonable for 1 person if prompt ambulance assistance was available. As discussed, for a person to need RN level care or 2:1 care for (potential) seizures, they would have to have a high-level of additional medical problems/equipment that lead to such severe compromise or need for intervention.* s47F - personal privacy

A recent significant literature review research paper on seizure monitoring devices concluded that *"there are limited data on which is the best sensor for each seizure type. It is likely that multimodal patient-specific detection systems will be needed to meet the complex requirements of seizure detection".* [31]

The table below is an overview of some of the devices. Evidence of efficacy and in what case a device might be chosen, could not be found for most device types.

Evidence of Efficacy

Device Type	Description	Primary Input	Evidence of efficacy	In what case would device be chosen?
Seizure mats/mattresses for beds	Will monitor a sleeping adult or child's convulsive seizures from under the mattress.	Movement	Allows nocturnal generalized tonic-clonic seizures detection. There is no need to place electrodes on the patient. Parameters can be adjusted for every patient. Only detects seizures with rhythmic movements. There is a weight limitation. Some find it uncomfortable. Low sensitivity. (Key H from Table B). [32]	Generalized tonic-clonic seizures, Focal dyscognitive seizures with motor phenomenon. (Key H from Table B)
Smart watches	Several types of Smart Watches with similar functions: helps detect seizures and monitor activity and sleep. Linked to the wearer's	Movement, Motion, GPS, electrical activity of skin		

[31] A. Ulate-Campos et al. "Automated seizure detection systems and their effectiveness for each type of seizure", Seizure
Volume 40, August 2016, Pages 88-101.
https://www.sciencedirect.com/science/article/pii/S1059131116300711

[32] A. Ulate-Campos et al. "Automated seizure detection systems and their effectiveness for each type of seizure", Seizure
Volume 40, August 2016, Pages 88-101.
https://www.sciencedirect.com/science/article/pii/S1059131116300711

Device Type	Description	Primary Input	Evidence of efficacy	In what case would device be chosen?
	mobile device with a Bluetooth® connection. Some can detect falls. [33]			
Pendants	When the user needs help they press the button, and the pendant will text and call emergency contacts. Each text message will show their location on Google Maps using the built-in GPS. When the call from the pendant is answered they can speak and listen 'hands free' through their pendant. [34]	User, GPS		
Harness/Drop Harness	Upper body harness that wraps around the user's waist, chest and torso, with an attached central handle running the length of the torso. [35]	Movement, Motion		
Socks (Babies)	Smart Sock fits snug on baby's foot and monitors their heart rate and oxygen levels while they sleep. [36]	Movement, heat rate		
Nappies (Babies)	Wearable device which attaches to baby's nappy and monitors abdominal movement. [37]	Movement, motion		
Oximeters	Measures oxygen saturation level, or the oxygen levels in blood. It can rapidly detect even small changes in how efficiently oxygen	Pulse	To date the reliability of these devices has not been robustly assessed in a patient population. [39] The Thoracic Society of Australia and New	

[33] Epilepsy Action Australia, Seizure Monitors & Wearable Technology [website], 2017, https://www.epilepsy.org.au/how-we-can-help/epilepsy-products, (accessed 16 August 2019).
[34] Epilepsy Action Australia, Fact Sheet: Seizure Safety Products, [website], 2019, https://www.epilepsy.org.au/wp-content/uploads/2019/07/Fact-Sheet-Seizure-Safety-Products.pdf, (accessed 19 August 2019).
[35] Epilepsy Action Australia, Fact Sheet: Seizure Safety Products, [website], 2019, https://www.epilepsy.org.au/wp-content/uploads/2019/07/Fact-Sheet-Seizure-Safety-Products.pdf, (accessed 19 August 2019).
[36] Epilepsy Action Australia, Fact Sheet: Seizure Safety Products, [website], 2019, https://www.epilepsy.org.au/wp-content/uploads/2019/07/Fact-Sheet-Seizure-Safety-Products.pdf, (accessed 19 August 2019).
[37] Epilepsy Action Australia, Fact Sheet: Seizure Safety Products, [website], 2019, https://www.epilepsy.org.au/wp-content/uploads/2019/07/Fact-Sheet-Seizure-Safety-Products.pdf, (accessed 19 August 2019).
[39] R. Mcdermott et al., Evaluating the accuracy of commercially available finger pulse oximeters in a hospital setting, European Respiratory Journal 2018. (https://erj.ersjournals.com/content/52/suppl_62/PA4452)

Device Type	Description	Primary Input	Evidence of efficacy	In what case would device be chosen?
	is being carried to the extremities furthest from the heart, including the legs and the arms. [38]		Zealand assert that their use in an unsupervised environment cannot be recommended. [40] Seizures which have little or no movement or sound and can only be detected with oxygen desaturation. [41]	
Camera Monitoring	Monitors sleep activity with time-stamped recordings of movements, can sound an alert if anything unusual is detected. [42]	Movement, motion		

Choosing a device type: guidance for physicians, families and researchers

A recent significant literature review research paper summarized current evidence, and offered suggestions on how to select the most suitable seizure detection device for each patient and provide guidance to physicians, families and researchers when choosing or designing seizure detection devices. However, it did conclude that there is limited data on which is the best sensor for each seizure type. The table below is a comparison of the available seizure prediction sensors.[43]

Note that some of these sensors are for clinical use.

KEY	Seizure detector	Primary input	Seizures detected	Advantages	Disadvantages
A	***Electroencephalogram (EEG)***	EPSP/IPSPs	Focal dyscognitive seizures, focal without dyscognitive changes and secondarily generalized, absence seizures	Gold-standard. Good sensitivities were achieved	Discomfort, stigmatization due to electrodes. Risk for movement artefact

[38] Epilepsy Action Australia, Fact Sheet: Seizure Safety Products, [website], 2019, https://www.epilepsy.org.au/wp-content/uploads/2019/07/Fact-Sheet-Seizure-Safety-Products.pdf, (accessed 19 August 2019).
[40] J. Pretto, Clinical use of pulse oximetry: Official guidelines from the Thoracic Society of Australia and New Zealand, 2013 (https://www.thoracic.org.au/clinical-documents/command/download_file/id/34/filename/Pretto_et_al-2014-Respirology.pdf)
[41] Epilepsy Action Australia, Seizure Monitors & Wearable Technology [website], 2017, https://www.epilepsy.org.au/how-we-can-help/epilepsy-products, (accessed 16 August 2019).
[42] Epilepsy Action Australia, Fact Sheet: Seizure Safety Products, [website], 2019, https://www.epilepsy.org.au/wp-content/uploads/2019/07/Fact-Sheet-Seizure-Safety-Products.pdf, (accessed 19 August 2019).
[43] A. Ulate-Campos et al. "Automated seizure detection systems and their effectiveness for each type of seizure", Seizure
Volume 40, August 2016, Pages 88-101.
https://www.sciencedirect.com/science/article/pii/S1059131116300711

KEY	Seizure detector	Primary input	Seizures detected	Advantages	Disadvantages
B	***Intracranial EEG***	EPSP/IPSPs	Focal dyscognitive seizures, focal without dyscognitive changes and secondarily generalized	Gold-standard. Good sensitivities, were achieved	Invasive procedure with potentially life-threatening complications
C	***Surface electromyography (sEMG)***	Muscle movement	GTCS, tonic seizures, hypermotor seizures	Early detection in tonic phase with one channel. Good sensitivity and night time detection	Only detects seizures with a motor component. Electrodes could detach, move or be uncomfortable
D	***Electrodermal activity (EDA)***	Sweating	GTCS, Focal dyscognitive seizures	Good detection rates, including FDS, better when combined with ACM	Susceptible to motion and pressure arti facts, could be uncomfortable
E	***Electrocardiography (EKG)***	Heart rate changes	Focal seizures, secondarily generalized seizures and GTCS	Heart rate is relatively easy to detect. Can be recorded from one channel. Higher signal to noise ration than EEG	Seizures without HR changes go undetected. HR changes occur in many everyday activities and seem to be patient specific. Electrodes might be uncomfortable or unstable on the long-term
F	***Accelerometry (ACM)***	Movement	GTCS, secondarily generalized, myoclonic, clonic, tonic and hypermotor seizures	Great sensibility, good night detection rates. User friendly	Only detects seizures with a motor component and when there is free limb movement. Battery system needs to be optimized
G	***Video detection systems***	Movement	Focal, hypermotor, myoclonic and clonic	No discomfort for patients in marker free video	Mainly detects seizures with a motor component. Limited to the area covered by video, the patient must be visible and properly placed. Attached markers could dislocate or produce discomfort
H	***Mattress sensors***	Movement, noise	GTCS, Focal dyscognitive seizures with motor phenomenon	Allows nocturnal GTCS detection. There is no need to place electrodes on the patient. Parameters can be adjusted for every patient.	Only detects seizures with rhythmic movements. There is a weight limitation. Some find it uncomfortable. Low sensitivity.
I	***Seizure-alert dogs***	Subtle behavioral changes are detected by the dogs	Focal dyscognitive seizures, GTCS	Alert before the seizure. Increase in QOL, possible reduction in seizure frequency	Few studies while the patient is on EEG. They also alarm to psychogenic seizures. Cannot detect while dogs sleep
J	***Cerebral oxygen saturation sensors***	Cerebral blood flow	GTCS, temporal lobe seizures	Can detect seizures up to 18min before clinical onset	Few studies, only in 2 seizure types

KEY	Seizure detector	Primary input	Seizures detected	Advantages	Disadvantages
K	***Near infrared spectroscopy (NIRS)***	Regional cerebral oxygenation	Focal dyscognitive seizures, focal without dyscognitive changes and focal with secondary generalization, absences	Good detection, including FDS	Big diversity in hemodynamic changes. Electrode could be uncomfortable and must be surrounded by a black cloth
L	***Implanted advisory system***	EPSPs/IPSPs	Focal seizures	Good detection, including FDS	Invasive procedure with potentially serious adverse effects

Future Research

A 2015 comprehensive research review [44]explored possibilities in the field of epileptology after analysing the current and existing applications of mobile phones in care of the epileptic patients worldwide. The review suggested that "mobile phone apps can be useful in the hands of the epileptic patients, their caregivers or the healthcare professionals themselves". It goes on to suggest that "A multi-disciplinary approach involving the collaboration of neurologists, electronic and electrical engineers, pharmaceutical companies and more importantly the patients themselves would be required to make such possibilities a reality"

From the research sourced little could be found regarding testing and trials of the monitoring devices. It is very clear that further research is required into the efficacy of seizure monitoring devices.

A 2017 research article [45]looked at standards for testing and clinical validation of seizure detection devices, and suggested that "the way studies are designed and reported is very heterogeneous and often confusing. It can be difficult to understand the level of evidence these studies provide". To help in designing and reporting studies on seizure detection devices, the study proposed a set of standards, specific for this field, with the goal to improve the quality of these studies, and to provide readers a clear-cut picture of the position of the studies in the clinical validation process. "This could be useful information for regulatory bodies too. Developing standards for testing and validating seizure detection devices requires in-depth knowledge of the field, because standards from trials on other types of medical devices can be difficult to extrapolate to seizure detection".

Evidence and efficacy of Seizure Alert Dogs

Overview

- The use of seizure dogs emerged around the mid 1990's. Around that time research on the subject appeared to be active, however there is very little recent research on the subject.

[44] L. Ranganathan et al., "Application of mobile phones in epilepsy care", International Journal of Epilepsy, Vol 2, No 1, pp. 28-37, 2015, https://www.sciencedirect.com/science/article/pii/S2213632015000044
[45] S. Beniczky and P. Ryvlin, "Standards for testing and clinical validation of seizure detection devices", Epilepsia, Vol 59, No S1, pp. 9-13, 2018, https://onlinelibrary.wiley.com/doi/10.1111/epi.14049

- There are two types of seizure dogs: Seizure Alert Dogs assist their human companions before a seizure occurs, and Seizure Response (or Seizure Assist Dogs) help during and after a seizure. [46]

- A popular theme in the research as to how a dog detects a seizure is that they "probably alert to subtle pre-ictal human behaviour changes, but may also be sensitive to heart rate or olfactory cues". [47]

- Research is not conclusive. There are mixed research outcomes, and the subject appears to remain controversial.

- There is inconsistent outcomes in the research regarding the accuracy of a seizure dog to detect a seizure.

- The majority of the research recommends that further research is required on the subject of accuracy in seizure dogs to alert an oncoming seizure.

NDIS Practice Guide – Epilepsy Reports

According to the NDIS Practice Guide – Epilepsy Supports, "there is insufficient evidence in published and refereed literature to support the use of epilepsy seizure assist dogs as an effective disability support" (Page 16, V1.0 2019-09-26)

Research Summary

- There are several types of seizures some of which are classified as epileptic.
- There is a broad range of causes and triggers which may apply to all seizure types. In some seizure types causes or triggers are unknown.
- A seizure alert device is a monitoring system that can detect when a person may be having a seizure and notify someone who can respond.
- There are several types of seizure monitoring devices using different type of sensory and input processes.
- All devices researched appear to be suitable for use by all age groups, except baby specific items.
- There is no solid evidence that seizure frequency increases or decreases depending on the age of the patient, and research in this area is limited.
- It appears that there is no evidence of efficacy of the devices. No research trials or tests could be sourced, and there is a running theme in the literature for the need for further research.

[46] Epilepsy Foundation, "Seizure-Alert Dogs: Just the Facts, Hold the Media Hype", [website], 2019, https://www.epilepsy.com/article/2014/3/seizure-alert-dogs-just-facts-hold-media-hype, (accessed 20 January 2020)
[47] S. Brown and L. Goldstein, "Can seizure-alert dogs predict seizures?", Epilepsy Research, Vol 97, No 3, pp. 236-242, 2011, https://www.sciencedirect.com/science/article/abs/pii/S0920121111003275

- Very little reference could be found with regard to how a patient may choose a particular device for a particular seizure type.

s47E(d) - certain operations of agencies

Reference List

A. Geerts et al., "Course and outcome of childhood epilepsy: A 15-year follow-up of the Dutch Study of Epilepsy in Childhood", Epilepsia, Vol 51, No 7, pp. 1189-1197, 2010, https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1528-1167.2010.02546.x

A. Ulate-Campos et al. "Automated seizure detection systems and their effectiveness for each type of seizure", Seizure
Volume 40, August 2016, Pages 88-101.
https://www.sciencedirect.com/science/article/pii/S1059131116300711

A. Ulate-Campos et al. "Automated seizure detection systems and their effectiveness for each type of seizure", Seizure
Volume 40, August 2016, Pages 88-101.
https://www.sciencedirect.com/science/article/pii/S1059131116300711

Australian Medical Association, "Epilepsy: 7 out of 10 children grow out of it", [website], 2019, https://ama.com.au/ausmed/epilepsy-7-out-10-children-grow-out-it, (accessed 9 December 2019)

Cedars Sinai, "Atonic Seizures", [website], 2019, https://www.cedars-sinai.edu/Patients/Health-Conditions/Atonic-Seizures.aspx?_ga=2.105746691.1656684614.1575939601-329177124.1575939601, (accessed 9 December 2019)
Cedars Sinai, "Simple Partial Seizures", [website], 2019, https://www.cedars-sinai.edu/Patients/Health-Conditions/Simple-Partial-Seizures.aspx?_ga=2.63216303.1656684614.1575939601-329177124.1575939601, (accessed 9 December 2019)

Epilepsy Action Australia, "Psychogenic non-epileptic seizures", [website], 2017. https://www.epilepsy.org.au/epilepsy-trainer-news-feature-psychogenic-non-epileptic-seizures, (accessed 26 November 2019).
Epilepsy Action Australia, Safety Products and Alarms, [website], 2019, https://www.epilepsy.org.au/e-360-edition-13-safety-products-and-alarms, (accessed 19 August 2019).

Epilepsy Action Australia, Seizure Types , [website], 2019, https://www.epilepsy.org.au/about-epilepsy/understanding-epilepsy/seizure-types-and-classification, (accessed 25 November 2019)

Epilepsy Foundation of America, Considering a seizure alert device, 2018 [online brochure], https://www.epilepsy.com/sites/core/files/atoms/files/DAS100_Seizure_Alert_Devices_09-2018_FINAL2.pdf, (accessed 19 August 2019).

Epilepsy Foundation, "Focal Onset Impaired Awareness Seizures (complex partial seizures)", [website], 2019, https://www.epilepsy.com/learn/types-seizures/focal-onset-impaired-awareness-seizures-aka-complex-partial-seizures, (accessed 9 December 2019)

Epilepsy Foundation, "Infantile Spasms (West's Syndrome) and Tuberous Sclerosis Complex", [website], 2019, https://www.epilepsy.com/learn/types-epilepsy-syndromes/infantile-spasms-wests-syndrome-and-tuberous-sclerosis-complex, (accessed 9 December 2019)

Epilepsy Foundation, "Seizure-Alert Dogs: Just the Facts, Hold the Media Hype", [website], 2019, https://www.epilepsy.com/article/2014/3/seizure-alert-dogs-just-facts-hold-media-hype, (accessed 20 January 2020)
Epilepsy Foundation, "Tonic Seizures", [website], 2019, https://www.epilepsy.com/learn/types-seizures/tonic-seizures, (accessed 9 December 2019)

Epilepsy Foundation, "Will I Always Have Seizures?", [website], 2019, https://www.epilepsy.com/learn/about-epilepsy-basics/will-i-always-have-seizures, (accessed 11 December 2019)

Epilepsy Foundation, The Role of Seizure Alerts, [website], 2019, https://www.epilepsy.com/learn/early-death-and-sudep/sudep/role-seizure-alerts, (accessed 19 August 2019).

Genetic and Rare Diseases Information Centre, "Pyridoxine-dependent epilepsy", [website], 2019, https://rarediseases.info.nih.gov/diseases/9298/pyridoxine-dependent-epilepsy, (accessed 9 November 2019)

J. Osborne et al., "Infantile Spasms and West Syndrome: An explanatory booklet for parents and for professionals", 2006, https://www.rch.org.au/uploadedFiles/Main/Content/neurology/20060215_InfantileSpasms_handout.pdf

John Hopkins Medicine, "Absence Seizures", [website], 2019, https://www.hopkinsmedicine.org/health/conditions-and-diseases/epilepsy/absence-seizures, (accessed 9 December 2019)

John Hopkins Medicine, "Tonic and Clonic Seizures", [website], 2019, https://www.hopkinsmedicine.org/health/conditions-and-diseases/epilepsy/tonic-and-clonic-seizures, (accessed 9 December 2019)

L. Ranganathan et al., "Application of mobile phones in epilepsy care", International Journal of Epilepsy, Vol 2, No 1, pp. 28-37, 2015, https://www.sciencedirect.com/science/article/pii/S2213632015000044

Mayo Clinic, "Grand mal seizure", [website], 2019, https://www.mayoclinic.org/diseases-conditions/grand-mal-seizure/symptoms-causes/syc-20363458, (accessed 28 November 2019)
Mayo Clinic, "Seizures", [website], 2019, https://www.mayoclinic.org/diseases-conditions/seizure/symptoms-causes/syc-20365711, (accessed 9 December 2019)

National Institute of Neurological Disorders and Stroke, "Febrile Seizures Fact Sheet", [website], 2019, https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Febrile-Seizures-Fact-Sheet, (accessed 28 November 2019)
National Institute of Neurological Disorders and Stroke, "Grand mal seizure", [website], 2019, https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Myoclonus-Fact-Sheet, (accessed 28 November 2019)
Queensland Paediatric Epilepsy Network, New Diagnosis of Epilepsy Fact Sheet", https://www.childrens.health.qld.gov.au/wp-content/uploads/PDF/qpen-new-diagnosis-booklet.pdf

S. Beniczky and P. Ryvlin, "Standards for testing and clinical validation of seizure detection devices", Epilepsia, Vol 59, No S1, pp. 9-13, 2018, https://onlinelibrary.wiley.com/doi/10.1111/epi.14049

S. Brown and L. Goldstein, "Can seizure-alert dogs predict seizures?", Epilepsy Research, Vol 97, No 3, pp. 236-242, 2011, https://www.sciencedirect.com/science/article/abs/pii/S0920121111003275

Warner, TA et al., 'Heat induced temperature dysregulation and seizures in Dravet Syndrome/GEFS+ Gabrg2+/Q390X mice', Epilepsy research, vol. 134, 2017, pp.1-8, https://www.sciencedirect.com/science/article/abs/pii/S0920121117302620, accessed 10 October 2019.

WebMD, "Common Epilepsy Causes and Seizure Triggers", [website], 2019, https://www.webmd.com/epilepsy/guide/epilepsy-causes, (accessed 9 December 2019)

WebMD, "What Causes Infantile Spasms?", [website], 2019, https://www.webmd.com/children/west-syndrome-causes, (accessed 9 December 2019)

Appendix A: NDIS Technical Advisory Team Survey

2018 NDIS Technical Advisory Team Survey of three experts in the field of Neurology and Epileptology.

Survey Responses

NOTE: Professor Mark Cook did not return responses.

Questions

1. Is face to face continuous monitoring of a person who experiences seizures ever required or recommended for a person (child or adult) with epilepsy only and no other comorbidities? (ie continuous watching of the person in case a seizure occurs).

Harvey	*Yes (but rare)*
Newton	*This would be a very rare situation. Most people with such severe epilepsy usually have co-morbidities.*
Cook	

2. If yes, in what circumstances would this be required? Please comment on different Epilepsy types and level of risk of seizures for different persons with Epilepsy (other than intractable epilepsy). Please provide details of the following:

- Type of observation and actions required
- Record keeping recommendations/ requirements
- Mandatory qualifications and experience of support workers

Harvey	*Typically infants with severe seizures disorders (eg. multiple hourly seizures with depressed airway/breathing/circulation during the seizures) who may have emerging developmental delays but not an established diagnosis of a comorbid disability. This is often provided by parents and carers who have been trained by medical and nursing staff. This may involve recording of seizure frequency/duration, giving regular medication, providing airway management +/- O2 if used at home, administration of midazolam, calling for ambulance support when necessary.*
Newton	*The situation here is likely determined by Lennox Gastaut Syndrome (LGS) where tonic seizures or atonic seizures (drop attacks) can be frequent and potentially injurious. Usually a parent or carer keeps close by while patient is on their feet. Recording the events is necessary as guide for medical review. Training in seizure care is usually provided by the Epilepsy support groups, such as Epilepsy Australia and Epilepsy Foundation Victoria.*
Cook	

3. Is face to face continuous monitoring of a person experiencing seizures ever required for a person (child or adult) with epilepsy where there are co-morbidities? (eg Intellectual disability, ASD, CP)

Harvey	*Yes, more commonly, as the underlying neurological problems causing such severe epilepsies tend to also cause other neurological comorbidities that may exacerbate the effects of seizures eg. tonic or tonic-clonic seizures in a child with CP* *Typically these would be children or adults with ID, CP, airway/feeding issues (eg. Rett syndrome, severe brain injuries, severe brain malformations) who have a high level of baseline disability and need for care who become additionally compromised by their seizures. These people would likely have parents/carers who need to respond to seizures with positioning, suctioning, maybe O2 and emergency medication. Monitoring would typically be assisted by oximetry, so that they don't need face-to-face.*
Newton	*Although uncommon, there are people with frequent and potentially risky seizures who need watching.*
Cook	

4. If yes, in what circumstances would this be required? Please comment on different Epilepsy types and level of risk of seizures for different persons with Epilepsy (other than intractable epilepsy). Please provide details of the following:

- Type of observation and actions required
- Record keeping recommendations/ requirements
- Mandatory qualifications and experience of support workers

Harvey	*Again, this would typically be in a child, adolescent or adult with severe epilepsy (such as Lennox-Gastaut syndrome resulting from a genetic disorder,*

	diffuse brain malformation or severe brain injury) having >hourly seizures or tendency to prolonged seizures. Management and training as above. Often such patients have severe neurological disabilities and the parents and carers are managing other around the clock issues such as positioning, airway, feeding.
Newton	*The circumstances are usually epilepsy with co-morbidity such as developmental or acquired brain disorders. Action may amount to positioning of the person during and after seizure, to airway management, emergency medication administration such as midazolam via buccal or nasal routes. Seizures are usually charted noting if medication is given, to allow better appraisal at next neurology clinic review. Basic seizure first aid and when necessary training in emergency medication administration is required. This is usually provided by Epilepsy support groups, with the help of guidelines provided by the treating neurologist.*
Cook	

5. Is face to face continuous monitoring of a person experiencing seizures ever required for a person (child or adult) with intractable epilepsy both with and without co-morbidities? (eg Intellectual disability, ASD, CP)

Harvey	*Potentially, in some instances. The seizures need to be of a type that the specific monitor can detect with extremely high reliability eg. movement detectors for TCS, apnoea monitor for seizures with apnoea.* *For the children/adults described above, oximetry would typically be used because they have limited mobility (oximeter won't fall off) and seizures compromise their breathing. Oximeters typically need to be rotated between digits, by the carer or parent.*
Newton	*See (4) above.*
Cook	

6. If yes, in what circumstances would this be required? Again, please comment on :

- Type of observation and actions required
- Record keeping recommendations/ requirements
- Mandatory qualifications and experience of support workers

Harvey	*This is a huge topic for which I have no particular expertise. Parents/carers typically research and try out different devices to find one that is suitable for their child. However, these are often for people with mild epilepsy having infrequent seizures to provide peace of mind, especially at night. For more expert opinion, I would suggest contacting Epilepsy Australia/Action or the team at St Vincent's Hospital Melbourne who work in this space.* *As discussed, the extremely high care patients with parents or in-house 1-on—1 carers would probably be using oximeters or apnoea mattresses. Other*

	devices need to be shown to be effective at detecting seizures and having low false alarm rates. The monitoring for infrequent seizures (to prevent SUDEP) in people with or without disability is a separate issue. In the absence of other disability, this is probably not an NDIS issue. I spoke with Mark Cook at SVHM who would be happy to speak with you.
Newton	*(Left blank)*
Cook	

7. What specific support is required at the time a person (adult or child) is having a seizure or in the post ictal period??

Harvey	*I am not aware of any high-quality medical evidence for the systematic use of "seizure alert dogs". However, I can imagine that there are individual cases in which a particular dog alerts carers to a particular person's specific seizures.* s47F - personal privacy
Newton	*This depends on the particular case in question. Some seizures have little recovery periods, others are much longer and require more oversight. If confused, there needs to be observation, reassurance if needed, and physical intervention, such as preventing a person from wandering in the confused state. Eg. If an exit door cannot be locked, a carer may stand in front of the door. Actual handling is best avoided in most cases. Should there have been an injury in the seizure, carer would report to supervisor on the nature of it to ascertain whether medical review is necessary.*
Cook	

8. Can this support be provided by a trained support worker or parent?
If not, what qualifications would be required in any circumstances?

Harvey	*See first aid advice on any of the epilepsy support group websites – positioning, monitoring, protecting, calling for emergency assistance if prolonged, administering midazolam if prescribed and trained, postictal care.*
Newton	*Yes, this is usually done by trained support worker or parent.*
Cook	

9. Can this support be provided by a trained support worker or parent?

If not, what qualifications would be required in any circumstances?

Harvey	*Yes.*

10. The agency has also been receiving requests to provide up to 2 support workers to accompany participants either in the home or out in community so there is support available to assist at all times in case of an emergency including administration of Midazolam, and resuscitation with respiratory bagging, administration of oxygen and trachea maintenance.

    i. Would 2 people ever be required to assist with management of a seizure when there is access to on call ambulance services? If so, in what circumstances?
    ii. What qualifications, if any, are required of the second person (if required)? Is there any reason a second person would be required in case of an emergency where there is access to ambulance services?

Harvey	*These would be exceptional cases in which there is a severe seizure disorder with severe underlying neurological disability. Superficially, it would seem reasonable for 1 person if prompt ambulance assistance was available.* *As discussed, for a person to need RN level care or 2:1 care for (potential) seizures, they would have to have a high-level of additional medical problems/equipment that lead to such severe compromise or need for intervention. This might be a line in the sand that contrasts NDIS and Health.*
Newton	*There are exceptional cases where due to patient's physical size, degree of immobility, duration and type of seizure when 2 people will better manage a seizure than one. It is very much dependent on the individual case. In my adult clientele, there are only 2 or 3 cases who come into this category.*
Cook	

11. Can the need for face to face monitoring be negated or reduced with the use of monitoring or alarm devices?

Newton	*This depends upon the type of seizure, the time of day/night and so on. The device needs to be sensitive without too many false alarms. Again, this has to be worked out on an individual basis.*
Cook	

12. If so, what monitoring devices would be appropriate for what types of epilepsy? Please comment on the evidence base for any monitoring/ alarm devices.

Newton	*Please see Simon Harvey & Mark Cook responses.*
Cook	

13. Is there any evidence for the use of seizure alert dogs for the monitoring and management of epilepsy?

Newton	*My review of the literature does not reveal a strong case at this point in time for seizure alert dogs.*

Cook	

Details of experts surveyed

Consultant	Detail	Contact
Dr. Mark Newton	Neurologist & Epileptologist ; Epilepsy specialist with experience with severe epilepsy and associated co-morbidities; senior staff from the Epilepsy Research Centre	**Epilepsy Research Centre** Profile: Link Epilepsy Research Centre Level 2, Melbourne Brain Centre 245 Burgundy Street Austin Health Heidelberg 3084 VIC AUSTRALIA Telephone: +613 9035 7330 Email: s47F - perso @unimelb.edu.au **Melbourne Uni:** Profile: Link
Dr Simon Harvey	Consultant Neurologist Director, Children's Epilepsy Program s47F - personal privacy s47F - personal privacy to work in the RCH Neurology Department, with additional appointments in the MCRI and University of Melbourne Department of Paediatrics.	**RCH** s47F - personal privacy @rch.org.au Phone: (03) 9345 s47F - personal priv Department of Neurology The Royal Children's Hospital 50 Flemington Road Parkville, Victoria 3052 Australia Profile: Link
Professor Mark Cook:	Currently Chair of Medicine at St. Vincent's Hospital, Professor Cook specialises in the treatment of epilepsy – his previous role was at St Vincent's as Professor and Director of Neurology. He is recognised internationally for his expertise in epilepsy management, particularly imaging and surgical planning.	**St Vincent's:** Level 5, Daly Wing, St Vincent's Hospital 41 Victoria Parade, Fitzroy VIC 3065 Phone: (03) 9231 s47F - persona Email: s47F - personal privacy Profile: Link **Melbourne Uni:** s47F - personal privacy @unimelb.edu.au Phone (03) s47F - personal privacy Profile: Link

Appendix B: NDIS Health Policy (Epilepsy monitoring through assistive technology)

Epilepsy monitoring through assistive technology Epilepsy assistive technology is to monitor seizures which directly improves the functional capacity of the participant and their abilities to undertake activities of daily living.	**NDIS Responsibility** The NDIS will fund this disability related health support **when it is a regular part of the participant's daily life and results from the participant's disability.** Epilepsy monitoring through assistive technology (seizure monitor alarm systems and seizure mats for beds). In this instance, the rationale for providing the assistive technology for epilepsy monitoring is because it may reduce or negate the need for a support worker to provide face to face monitoring. **Health System Responsibility** All supports provided in a hospital setting or **when not a regular part of the participant's daily life or resulting from the participant's disability**

Guide Dogs for Vision Impaired Adolescents

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: What are the outcomes (positive and negative) for young teenagers matched with guide dogs?

Date: 2/5/23

Requestor: Anita s47F - personal privacy, Liz s47F - persona

Endorsed by: Yuemei s47F - person

Researcher: Stephanie s47F - personal privacy Aaron s47F - personal privacy

Cleared by: Aaron s47F - personal privacy

1. Contents

2. Summary

From the available evidence, it is unclear whether there are any benefits or risks associated with the use of guide dogs for younger adolescents. It is unclear whether use of guide dogs for younger adolescents is associated with any better, worse or different outcomes compared to use of guide dogs for adults.

Very little published research exists on the subject. Just two studies describe the potential benefits and risks of adolescent guide dog use. Both studies are descriptive qualitative studies of the lowest level of evidence.

Many claimed or predicted effects are suggested to be similar for adult guide dog use. Benefits may include improvements to mobility, safety, independence, confidence and social participation. Risks or drawbacks may include cost and time expenditure, allergies, stigma and public access issues.

Factors particular to younger adolescents include risk of unwanted attention when unaccompanied in public and potential to improve independence and confidence as young people transition to adulthood. In addition, there is a suggestion that the guide dog may be used in a modified form as a capacity building support for young people.

Stronger evidence exists for the benefits and risks of other service animals for younger adolescents. However, it is not clear whether this literature can be applied to guide dog use.

3. Current practice of matching guide dogs with adolescents

The evidence base examining the use of guide dogs for adolescents is minimal. Most guide dog programs do not match dogs with people under 16 years old (Gavrok et al, 2018; Walther et al, 2017; Guide Dog Users, Inc., 2020). The US-based Guide Dog Users, Inc. surveys guide dog schools in the USA. Of the 12 respondents to the 2020 survey, 10 stated a lower age limit of 15-18. Two schools did not have a lower age limit but “will consider teenagers on an individual basis” (Guide Dog Users, Inc., 2020). The UK-based Guide Dogs organisation does not have a minimum age limit but requires all applicants to have a certain level of fitness, mobility and orientation skills (Guide Dogs UK, n.d.). Health Direct, the Australian government funded health information website, states that guide dogs “chosen for their good temperament and are suitable for anyone from children of school age to seniors” (Guide Dogs, 2021).

In April 2021, Seeing Eye Dogs Australia ran a story on their website about Ollie and his guide dog Sadie. At 14 years old, Ollie was the youngest person to be matched with a guide dog from Seeing Eye Dogs. The article flags a “change of thinking around age and Seeing Eye Dogs” and continues:

> Being matched with a Seeing Eye Dog is quite exciting for our clients, but it’s also a serious commitment to ensure the match is successful. In the past we have traditionally

matched Seeing Eye Dogs with clients over the age of 18, but as we continue to evolve as an organisation, we're looking at expanding who we work with.

Matching a Seeing Eye Dog with a handler comes down to a number of factors. Ollie has strong orientation and mobility skills and is committed to developing his skills as a dog handler and we're confident the match will be successful.

Ollie and Sadie are an exciting match for Seeing Eye Dogs. By the time Ollie finishes school, he'll be an experienced Seeing Eye Dog handler which will provide added independence as he moves into further education or employment and we're excited about replicating that with other young people in the future (Seeing Eye Dogs Australia, 2021).

Seeing Eye Dogs Australia are also running camps for teenagers 12 to 18 years old to, "help young participants understand what is required to work with a Seeing Eye Dog and see if this is the best fit for their needs. The program will also help improve independence, orientation and mobility skills" (Seeing Eye Dogs Australia, 2023). VisAbility Tasmania (n.d.) also offers a guide dog introduction camp for teenagers.

4. Benefits and risks

4.1 Benefits and positive outcomes

Benefits of guide dogs for adolescents are unclear. We found no studies showing evidence of efficacy for adolescents.

Anecdotal evidence of improvements to mobility and quality of life are described online in news articles and testimonials (for example, Seeing Eye Dogs Australia, 2021; Seeing Eye Dogs Australia, 2023).

A recent systematic review from Lindsay and Thiyagara (2021) examines the outcomes of service dog use for children and adolescents under 18 years old. They consider service dog use broadly to include guide dogs, mobility assistance dogs, hearing dogs, diabetes alert dogs and emotional support dogs. Only two articles specifically investigating guide dog use for young people were included for review and both were descriptive qualitative studies with the lowest level of evidence (Gavrok et al, 2018; Worth et al, 2013).

Worth et al (2013) recounts the experience of visually impaired 16 – 25 year olds, based on an unavailable PhD thesis from 2009. Benefits described by participants include:

- less reliance on spatial memory as they don't need to remember specific details of the environment like position of lamp-posts and telephone boxes
- improved social relations with people in public.

These results were not presented systematically and it was not reported which young people or how many of them experienced any particular benefit.

Gavrok et al (2018) is a small-sample interview-based study of participants in a guide dog introduction camp for visually impaired 12 – 18 year olds. Four adolescents (13, 13, 15 and 18 years old) participated in the interviews along with parents and camp instructors. The aim of the study was to "explore expectations regarding benefits/challenges that adolescents could experience from a guide dog" (Gavrok et al, 2018, p.19). The authors find that participants, their parents and the instructors believe the use of a guide dog will assist them or their children with mobility, safety, confidence, independence, and social interaction.

The authors' discussion notes these potential benefits while considering reasons the effect might not be what the study participants assume. They note, for example, that benefits in mobility may not be immediately achieved as younger people would likely require support from their parents. A parent acting as facilitator could mean "the mobility benefits provided by a facilitated guide dog would be equivalent to what a parent could provide alone, therefore rendering the dog redundant" (2018, p.20). The authors conclude by reconceptualising the role of the guide dog:

> adolescents are unlikely to receive some of these benefits due to constraints in their physical abilities and capacity to be responsible for their dog. While these constraints currently render adolescents ineligible to receive a guide dog, we propose a revised facilitated service dog model, in which dogs trained to provide support, but not necessarily to guide, are able to benefit adolescent owners in many critical ways, while also helping to prepare them for when they are able to receive a fully trained guide dog (Gavrok et al, 2018, p.26).

So, while Gavrok et al expect benefits from adolescent's use of guide dogs, they argue that the benefits are most likely to be achieved if the animal is not thought of as a guide dog.

This suggestion is anticipated by the idea of a 'visual companion dog' for young children:

> Children's Visual Companion Dogs (CVCD) are building bridges to independence and mobility for blind youth and their families. These life changing dogs increase confidence, self-esteem and stability, and they improve posture, gait and pace for blind and low-vision children while offering a unique and innovative means of travel (OccuPaws Guide Dog Association, n.d.).

The visual companion dog has been described in a single small-sample interview study. The author notes that the visual companion dog is not a guide dog as "children's visual companion dogs are trained and used as part of a unit or triad that includes the parent, the child, and the dog" (Tellesfon, 2012, p.306). The visual companion dog is a capacity building support aimed to teach the child orientation and mobility skills as the adults gradually releases control of the situation to the child. The strategy is used for visually impaired children as young as 3.

There is more substantial evidence available for younger people's use of service dogs in general. Most of the studies reviewed by Lindsay and Thiyagara (2020) describe a benefit in at least some area such as mobility, safety, physical or mental health, quality of life, self-confidence, social interaction or independence.

4.2 Risks and negative outcomes

Gavrok et al state that providers have "sound reasons" for not matching guide dogs to younger adolescents. These reasons are "concerns surrounding an adolescent's ability to ensure a dog's well-being, as they may have lower levels of maturity, responsibility, and ability to ensure the care and safety of their dog and themselves" (2018, p.19). However, their reference for this claim is an article discussing assistance dogs for children with developmental disabilities and may not translate to the effects of guide dogs for visually impaired adolescents.

In Worth (2013), having a guide dog is seen by the participants as a sign of maturity. However, as guide dogs may lead to unprompted social interaction, the dog can often draw unwanted attention. This may be a risk for younger adolescents travelling unaccompanied.

Lindsay and Thiyagara (2021) note some challenges of younger people's use of service dogs in general. These include:

- time spent caring for the dog
- associated costs
- child inadvertently hurting the dog
- effect of child's maturity on the service dog's performance
- allergies
- the dog's behaviour
- public access issues and stigma.

5. References

Gravrok, J., Howell, T., Bendrups, D., & Bennett, P. (2018). Adapting the traditional guide dog model to enable vision-impaired adolescents to thrive. *Journal of Veterinary Behavior*, *24*, 19-26.

Guide Dogs UK. (n.d.). Frequently Asked Questions. https://www.guidedogs.org.uk/faqs/guide-dogs/

Guide Dogs. (2021). Health Direct. https://www.healthdirect.gov.au/guide-dogs

Guide Dog Users, Inc. (2020). *GDUI School Surveys*. https://guidedogusersinc.org/resources/gdui-school-survey/

Lindsay, S., & Thiyagarajah, K. (2021). The impact of service dogs on children, youth and their families: A systematic review. *Disability and Health Journal*, *14*(3), 101012. https://doi.org/10.1016/j.dhjo.2020.101012

OccuPaws Guide Dog Association. (n.d.). *Visual Companion Dog*. https://occupaws.org/programs/childrens-visual-companion-dog/

Seeing Eye Dogs Australia. (2021). *Puppy love: Youngest person to ever receive Seeing Eye Dog finally meets his match*. Vision Australia. https://seda.visionaustralia.org/news/ollie-and-sadie-match

Seeing Eye Dogs Australia. (2023). *Innovative Youth Camp Breaking Barriers*. Vision Australia. https://seda.visionaustralia.org/news/2023-01-19/innovative-youth-camp-breaking-barriers

Tellefson, M. J. (2012). A Perspective on Teaching Early Harness Travel to Young Blind Children Using Children's Visual Companion Dogs. *Journal of Visual Impairment & Blindness*, *106*(5), 306–312. https://doi.org/10.1177/0145482X1210600507

VisAbility Tasmania. (n.d.). *Test Drive a Guide Dog*. https://www.visabilitytas.com.au/latest-news/mobility-and-independence-youth-test-drive-a-guide-dog/

Walther, S., Yamamoto, M., Thigpen, A. P., Garcia, A., Willits, N. H., & Hart, L. A. (2017). Assistance Dogs: Historic Patterns and Roles of Dogs Placed by ADI or IGDF Accredited Facilities and by Non-Accredited U.S. Facilities. *Frontiers in veterinary science*, *4*, 1. https://doi.org/10.3389/fvets.2017.00001

Worth, N. (2013). Visual Impairment in the City: Young People's Social Strategies for Independent Mobility. *Urban Studies*, *50*(3), 574–586. https://doi.org/10.1177/0042098012468898

Accreditation of Assistance Animals

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 does the Agency consider to be an 'accredited assistance animal provider?

What are the relevant state-based legislation/accreditation requirements for each state? How do they determine suitability of a provider in each state?

What are the implications if NDIS funding was provided under the Commonwealth DDA but not the law of the state or territory in which the participant resides? Are there legal implications for public access and what are these?

What are the best practice approaches to Assistance Animal training/certification?

Date: 5/5/2022

Requestor: Liz s47F - persona

Endorsed by (EL1 or above): Yuemei s47F - pers

Researcher: Stephanie s47F - personal privacy

Cleared by: Megan s47F - personal privacy

1. Contents

2. Summary

The *Disability Discrimination Act 1992* (Commonwealth) states an animal can meet the criteria of being an assistance animal (AA) in three ways:

1. State accreditation
2. Territory accreditation or;
3. Trained through an accredited training organisation or trained independently to meet the needs of a person with a disability.

All users of AA have public access rights under the *Disability Discrimination Act 1992* (Cth) regardless of whether the handler has a Public Access Test card, ID card or if the AA is wearing a special harness (City Services, n.d.).

Under the *Disability Discrimination Act 1992* (Cth) it is not considered discrimination to ask a person for proof an animal is a legitimate AA. If proof cannot be provided it is also not considered discrimination to refuse entry or ask the person to leave the premises. Therefore, the introduction of accreditation for AA and public access tests by Queensland, South Australia, Western Australia, and the Australian Capital Territory enable a person to gain formal recognition for their AA and receive an accreditation card that can be produced on demand.

The NDIS Guidelines have clear parameters for funding Assistance Animals. An AA must be trained by an **accredited organisation**, perform **3 tasks or behaviours** to support the

individual with a disability and pass a **public access test**. The NDIS Guidelines has additional criteria defining AAs compared to the legal definition in the *Disability Discrimination Act (Cth)*. **The benefit of encouraging a participant to use an accredited AA training organisation for their AA is that upon successful completion they receive a handler's card. Producing this card on request may reduce the number of negative social events experienced by a participant when in public if they are asked for proof that their dog is a legitimate assistance dog.** RES 239 Animal Assisted Therapy and Assistance Animals provides additional information regarding the evidence of stigma and discrimination experienced by users of assistance animals.

3. Definition of Assistance Animal

The legal definition of an Assistance Animal, set out by section 9 (2) of the *Disability Discrimination Act 1992* (Commonwealth), is a dog or animal that:

a) is accredited under a law of a State or Territory that provides for the accreditation of animals trained to assist a person with a disability to alleviate the effect of the disability; or

b) is accredited by an animal training organisation prescribed in the regulations; or

c) is trained:

i. to assist a person with a disability to alleviate the effect of the disability; and

ii. to meet standards of hygiene and behaviour that are appropriate for an animal in a public place.

Under the *Act*, an individual is free to choose how their assistance dog is trained. There is no one prescribed way for an animal to meet the definition of an AA. As long as the individual using the AA has the means to prove the animal is a genuine AA it does not matter under this Act how the animal is trained. However, a person using an AA must be able to prove that the animal is a genuine AA, and business owners or carer takers of public spaces and public transport have the right to refuse entry if evidence is not provided (Human Rights Commission, 2016). Methods of proof can be a letter from a medical specialist confirming the disability and AA, it could be an identification card obtained after being trained by an accredited training organisation, or it could be by providing a valid state Public Access Test card.

The National Disability Insurance Scheme differs in the definition of what is an AA. As described in NDIS Guidelines (NDIS, 2021):

"An assistance animal is an animal specially trained by an accredited assistance animal provider to help you do things you can't do because of your disability….The La Trobe University report defines assistance animal as "an animal that is trained to perform at least 3 tasks or behaviours which mitigate the effects of a person's disability". This means an assistance animal that has been trained to do at least 3 specific thing that you need, but can't do because of your disability."

The NDIS has taken on a definition recommended by the authors of a 2019 NDIS commissioned report "La Trobe University Report – Key terms for animals in disability assistance roles". In this report, the authors say:

> "Assistance animal is defined, building on the definition in the Australian Commonwealth Disability Discrimination Act, as an animal that is trained to perform at least three tasks or behaviours which mitigate the effects of a person's disability….They must also be trained to a high level of obedience. This enables them to access public spaces that are typically off-limits to animals..." (Howell et al, 2019, p. 7).

In this report, Howell et al (2019, p. 12) says:

> "There are no official regulatory bodies or training standards supported by the Disability Discrimination Act. There are, however, numerous organisations in Australia dedicated to training assistance animals, and breeding/sourcing of animals, training, and accreditation processes differ between these organisations. Some provider organisations fall under an umbrella such as Assistance Dogs International (ADI) or the International Guide Dog Federation (IDGF)."

Further in this report, Howell et al (2019, p. 20) advises:

> the "current legal definition is vague, particularly in Part (C). For this reason, we recommend adopting the standards of umbrella organisations such as ADI or IGDF, when determining whether an animal is sufficiently trained to access public spaces and can perform at least three specific tasks that 'alleviate the effect' of the owner's disability."

Upon communication with Assistance Dogs International (ADI) requesting background information relating to how the organisation developed the definition of AA, I was advised (via email, 27/4/22):

> "ADI member organisations determined our definitions in the early 1990's. when ADI was formed. The US American with Disabilities Act (1990) states that a Service Animal must perform at least one task to mitigate a disability. ADI members determined that our standards and definitions should be stronger, so they decided on three tasks to mitigate an individual's disability."

Communication from Howell regarding the definition of AA stated (via email, 28/4/22):

> "I do agree with the US law and ADI that it is important that assistance dogs be trained to perform specific tasks that mitigate the impact of the person's disability. Assistance animals need to be differentiated from emotional support animals (ESA), who require no specific training of any kind. Trained tasks are one way to tell them apart from ESAs. That is why we recommended that tasks be part of the definition of an assistance animal."

This communication from Howell appears to overlook the fact that the Disability Discrimination Act 1992 states an AA must be "trained to assist a person with a disability to alleviate the

effect of the disability". By recommending an animal perform three tasks, it sets the bar higher for an animal to be considered an AA. This may unintentionally exclude some animals from being considered an AA because they perform only one task or behaviour, no matter how significant, that helps alleviate the effect of a disability. Additionally, emotional support animals and therapy animals have no legislative protection and no public access rights which already differentiates them from AAs.

A comprehensive search of the Administrative Appeals Tribunal (AAT) outcomes did not reveal any decision made with respect to the stricter definition of AA by NDIS requiring that an AA must perform at least three tasks. However, the condition that an AA was "specially trained by an accredited assistance animal provider" has been successfully challenged. The case between Nottle and National Disability Insurance Agency [2021] AATA 1014 (9 April 2021) related to funding for acquisition, training and maintenance of a hearing assistance dog where the participant, an experienced dog trainer, requested funding for a second assistance dog as her current dog was nearing retirement. Part of the response from NDIS was that Nottle was not proposing to have an accredited trainer for the assistance dog but wanted to take the responsibility of training the dog herself. The only accredited trainer in her region would not allow a second dog at home, which would not allow Nottle to also keep her older assistance dog. The Tribunal found Nottle had the capability to acquire and train the dog herself and determined the NDIS decision be set aside.

In another legal case, in the Full Court of the Federal Court between Mulligan V Virgin Australia Airlines Pty Ltd [2015] FCCA 157, Mulligan claimed Virgin Airlines discriminated against him by refusing to allow his assistance dog. The assistance dog had been trained by a dog training school, but not one that was 'accredited'. The Court found that Virgin's conduct amounted to unlawful discrimination under the DDA. Specifically, that "an animal may be an AA under the DDA if it has received relevant training, regardless of who has provided that training" (Human Rights Commission, 2016).

4. State and Territory Legislative Requirements

4.1 New South Wales

AA in New South Wales are covered by the *Companion Animals Act 1998* (NSW). The definition of AA is aligned with the *Disability Discrimination Act 1992* (Commonwealth). It is noted that currently neither the Commonwealth nor New South Wales laws provide for the accreditation of AA (Office of Local Government, 2022).

The Office of Local Government (2022) highlights that a person with a disability is free to choose how their AA is trained, however the method must allow them to provide proof that the training meets the definition of an AA as per the *Companion Animals Act 1998* (NSW)/ *Disability Discrimination Act 1992* (Commonwealth). Staff in charge of access to public places and public transport are entitled to request reasonable proof the animal is a genuine AA (Office of Local Government, 2022). Staff may be guided by their organisation's policies.

Councils can request proof an animal is a legitimate AA, which may include evidence: of a disability, the animal is trained to alleviate the disability, and the animal is trained to meet standards of hygiene and behaviour appropriate for an animal in a public place (Office of Local Government, 2022). An animal does not need to be registered with their local council as an AA under the *Companion Animals Act 1998* to be permitted access to a public place or public transport (Office of Local Government, 2022).

To take an AA on public transport the handler must have an accepted type of accreditation – access can be refused if valid accreditation cannot be produced when asked. Accepted accreditation includes:

- AA Permit issued by Transport for NSW (Transport for NSW, n.d.) – to obtain a permit an individual needs a medical certificate confirming the disability within the meaning of the *Disability Discrimination Act 1992* (Commonwealth), a document showing the AA has been registered with the handler's local council (where relevant), a colour photograph of the AA, documentation dated within the last 6 months from either an organisation registered with the Transport for NSW (see below), an organisation not registered with the Transport for NSW or the individual themselves detailing the skills and action the animal has been trained to undertake and how these alleviate the effects of the disability, how they meet the appropriate behaviour and hygiene standards for a public place and how the animal is controlled. Current registered organisations include Assistance Dogs Australia, Centre for Service and Therapy Dogs of Australia Pty Ltd, Hans van Heesbeen t/a Service Dog Training, Integra Service Dogs Australia, K9 Tales Pty Ltd, Miracle Assistance Dogs Inc, Personal Assistance Dog Solutions, Pets Education Training Support, Smart Pups Assistance Dogs for Special Needs Children Inc.
- Accreditation from organisations endorsed by Transport for NSW – Australian Lions Hearing Dogs, MindDog Australia, Guide Dogs Australia and Vision Australia Seeing Eye Dogs (Transport for NSW, 2021).
- Interstate accreditation recognised by Transport for NSW – Victorian Public Transport AA Pass, WA Department of Local Government Public Access Permit, Queensland Government Handler Identity Card, SA Dog and Cat Management Board Pass, and additional passes accepted in SA (Assistance Dogs Australia Pass, Righteous Pups Australia, Royal Society for the Blind) (Transport for NSW, 2021).

4.2 Victoria

The rights of guide dog users is covered by the *Disability Discrimination Act 1992* (Commonwealth) and *Domestic Animals Act 1994* (Vic), both overriding the Health Act that prohibits dogs from entering food premises (Agriculture Victoria, 2022). The *Equal Opportunity*

Act 2010 (Vic) protects people with disabilities from discrimination, including if they have an assistance dog.

Under the *Equal Opportunity Act 2010* (Vic), an assistance aid includes an assistance dog that alleviates the effects of a person's disability. It is considered that if a person is accompanied by an assistance aid, the aid is to be taken as a characteristic of that person. Therefore, treating a person differently due to the presence of their assistance aid is considered discrimination (*Equal Opportunity Act 2010* (Vic)).

Assistance dogs are required to be; non-aggressive, obedient to the handler, quiet/ no barking, experience in real life situations, calm in confined and crowded spaces, and calm in noisy and stressful situations (Agriculture Victoria, 2022). Victoria does not have a Public Access Test for AA, however it is strongly recommended trainers use the previous requirements as a guide to minimum standards of behaviour and hygiene.

To use public transport with an AA, an AA Pass is required (note: guide dogs, hearing dogs and guide dogs in training do not require this pass). To apply, an individual needs to provide information regarding the trainer including their qualifications, AA card number if applicable, description of animal, photograph of the animal, health professional declaration from AHPRA registered professional confirming the AA information is accurate (Public Transport Victoria, 2019).

4.3 Queensland

The *Guide, Hearing and Assistance Dogs Act 2009* (Qld) aims to assist people with an AA to have independent access to the community and ensure the quality and accountability of guide, hearing and assistance dog training services (Disability Services, 2009). This Act reaffirms an individual's right of access if they are supported by an AA. The *Guide, Hearing and Assistance Dogs Act 2009* (Qld) does not override the rights of the *Disability Discrimination Act 1992*, therefore even if a dog does not display an approved badge they still have access rights and if a person with a disability feels they have been discriminated against they have the right to lodge a complaint under the *Disability Discrimination Act 1992* (Disability Services, 2009).

However Part C of the Public Access Test, obtaining a handler identity card, states:

"It is a requirement under the *Guide, Hearing and Assistance Dogs Act 2009* (Qld) that a person has a Handler Identity Card to identify themselves as a person who is accompanied by a guide, hearing or assistance dog, certified to access public places, places of accommodation and public passenger vehicles."

To clarify the situation, on the 20th April 2022 I called the Queensland Guide, Hearing and Assistance Dogs Office and was advised it was mandatory for assistance dogs to be certified otherwise a person could not take them out in public. When I pointed out that people are protected under the DDA she said dogs must be certified to maintain quality and safety of

assistance dogs and assistance dog trainers. However, in resources for businesses provided by the same Queensland Government office it clearly states:

"It should be noted that the Commonwealth *Disability Discrimination Act 1992* also provides access rights. People from interstate may not have Queensland identification but, in Australia, all people with a disability who are accompanied by a support animal are provided with the right of public access under the DDA, which makes it unlawful to discriminate against a person on the grounds of that person's disability."

In another resource titled: Legislation and Public Access, it states legislation supporting the rights of people with a disability to have the same access to public places, public passenger vehicles and places of accommodation are the Commonwealth *Disability Discrimination Act 1992* and the *Guide Hearing and Assistance Dogs Act 2009* (Qld).

On 3rd May 2022, I received email confirmation from the Guide Hearing and Assistance Dogs Office, Queensland Government, that "certification of a guide, hearing and assistance dog under Queensland's *Guide, Hearing and Assistance Dog Act 2009* (the GHAD Act) is not mandatory however, it is strongly recommended."

Dogs can be certified under the *Guide, Hearing and Assistance Dogs Act 2009* (Qld) if they (Department of Seniors, Disability Services and ATSI Partnerships, 2018):

- Can perform physical tasks and behaviours to assist a person with a disability in a way that reduces that person's need for support
- Can pass a public access test conducted by an approved trainer or institution
- Are not a restricted breed under the Local Government Act 1994
- Are desexed and vaccinated
- Have not been declared a dangerous dog under local law

Dogs must pass a public access test to become certified to ensure they are safe to take in public places or public passenger vehicles. A dog that displays aggressive, uncontrolled or unhygienic behaviour will not pass the test (Disability Services, 2009). If an individual or business exercising control of a public place or public vehicle has doubts of an AA authenticity, it is reasonable to ask to see the person's ID card to ensure the dog is certified under the Act (Disability Services, 2009). There are penalties for people and businesses who do not allow access to certified AA (Department of Seniors, Disability Services and ATSI Partnerships, 2018).

A long list of Australia-wide training services approved under the *Guide, Hearing and Assistance Dogs Act 2009* (Qld) can be found at Approved Trainers and Training Institutions.

4.4 South Australia

Recognition of assistance dogs in South Australia is under the *Dog and Cat Management Act 1995* (Sth Aust) (Dog and Cat Management Board, n.d.). There is no recognition for companion dogs, therapy dogs or emotional support dogs.

Assistance dogs can only be accredited under the *Dog and Cat Management Act 1995* (Sth Aust) by either the Dog and Cat Management Board or the following prescribed accreditation bodies: Royal Society for the Blind, Guide Dogs Australia, Lions Hearing Australia, Assistance Dogs Australia, Righteous Pups Australia, Vision Australia, Australian Veterinary Behaviour Services and Integra Service Dogs Australia (Dog and Cat Management Board, n.d.).

To apply for accreditation through the Dog and Cat Management Board, the handler needs to demonstrate the need for an AA, such as medical certificate detailing the disability and how the AA alleviates the effects of the disability, and relevant training of the AA indicating how the dog is trained to alleviate the effects of the disability and meets hygiene and behaviour standards, such as a certificate from a veterinarian or training organisation (Dog and Cat Management Board, n.d.).

The Dog and Cat Management Board (n.d.) highlight it is not discrimination to ask a person to leave a public place if they are unable to produce evidence the dog is an AA or if they don't meet appropriate standards of hygiene or behaviour. Dogs that are accredited under the *Dog and Cat Management Act 1995* (Sth Aust) are issued with an identity card that the handler can show when requested.

For dogs being claimed as an AA under the Disability Discrimination Act 1992 (Commonwealth), the handler will need evidence of both the need for an AA, such as a medical certificate stating they have a disability and the animal alleviates the effects of the disability, and evidence of appropriate training from a veterinarian or training organisation.

The Dog and Cat Management Board can only accredit dogs as an AA. The dog can be any breed but must be trained specifically to alleviate the effects of the disability. A veterinarian must declare the dog physically fit and not dangerous, a nuisance or menace. A dog does not need to be wearing a harness or jacket under South Australian or Commonwealth legislation (Dog and Cat Management Board, n.d.).

Dogs accredited interstate are not automatically accredited in South Australia. Individuals need to contact the Dog and Cat Management Board to get information specific to their situation before relocating.

4.5 Western Australia

It is not mandatory for an assistance dog to be accredited, however under Commonwealth law the handler of an AA has the onus to prove: they possess a disability, the dog is needed for the disability and the dog is suitably trained to be taken into public areas (Department of Local

Government, Sport and Cultural Industries (DLGSCI), 2021). For dogs not formally accredited, the handler may have difficulty proving the dog is a genuine AA and might increase the chance that the dog will be refused entry to public areas.

The DLGSCI provides an accreditation system for AA under the *Dog Act 1976* (Western Aust). To be approved, the dog and handler must pass the public access test, which is the minimum standard to be considered safe to access public areas and public transport (DLGSCI, 2021). Independent Public Access Test assessors are approved by the government. Once a dog is approved, the dog has an initial 6 month probationary period and then moves onto a 2 year approval. The handler is issued a card to provide evidence upon request that the dog is a genuine AA (DLGSCI, 2021). The card should always be carried by the handler so it can be produced if requested by an authorised person.

People with AA trained by the following organisations are automatically granted public access rights under the *Dog Act 1976* (Western Aust): Assistance Dogs Australia, Lions Hearing Dogs, Seeing Eye Dogs Australia, VisAbility WA, Royal Guide Dogs Association of Australia and affiliated bodies (DLGSCI, 2021). A dog that is accredited under a law in another state or territory has public access rights in WA under the *Dog Act 1976* (Western Aust).

People can also choose to train their assistance dog privately. Public access rights for privately trained dogs may be granted on application to the department after the applicant has demonstrated a need for the assistance dog and the dog meets the training criteria (DLGSCI, 2021).

4.6 Tasmania

The *Guide Dogs and Hearing Dogs Act 1967* (Tas) applies to guide dogs and hearing dogs but not assistance dogs (Department of Premier and Cabinet, n.d.). *The Disability Discrimination Act 1992* (Commonwealth) says a person cannot be discriminated against for having an AA or dog, however a person with an assistance dog can be asked to show proof the dog is an AA and trained to meet the standards of hygiene appropriate for a dog in a public place. No further information found with respect to AA training regulations.

4.7 Australian Capital Territory

The ACT has a legislative framework within Part 5 of the *Domestic Animals Act 2000* (ACT) that allows for AA to be accredited as meeting the ACT's public access standards. The accreditation is voluntary but clarifies the rights of access for people with a disability who use AA (City Services, n.d.). Once accredited, the Registrar of Domestic Animals may register the AA and issue the handler with an ID card for up to 2 years.

The voluntary public access test involves providing evidence of a disability from a medical practitioner, veterinarian declaration that the animal meets health requirements, and a 2-3 hour test conducted by an ACT registered trainer and assessor (City Services, n.d.).

Approved trainers are (City Services, n.d.):

- Isabela Lisiecka, Wooft Dog Training https://www.wooft.net/
- Jessica McNamara, ABCDOG Training https://www.abcdog.biz/
- Dee-Anne Gunter dalo7@ymail.com
- Tessa Stow, K9 Support http://www.k9support.com.au/
- Jessica Torrance, Assistance K9 https://www.facebook.com/assistancek9
- Emelia Wilmot, Paws for Assistance Dog Training https://pawsforassistance.com.au/

A person with accreditation under a recognised organisation or other jurisdiction can apply to have their AA registered by providing evidence of the accreditation without undertaking the public access test (City Services, n.d.).

AA accredited by organisations that meet the ACT standards of behaviour and hygiene include (City Services, n.d): Assistance dogs Australia, Australian support dogs, Guide Dogs Australia and their affiliated bodies (NSW/QLD/SA/NT/TAS/VIC/WA), Integra Service dogs Australia, mindDog Australia, Seeing Eye Dogs Australia – Vision Australia, any AA organisation, Australian or International, that is formally recognised by Assistance Dogs International and the International Guide Dog Federation.

4.8 Northern Territory

At the time of this research, minimal information regarding AA was found in relation to Northern Territory regulations. The *Disability Services Act 1993* (NT) does not reference AAs. Limited council information was located that highlighted assistance dogs are excluded from by-laws relating to registration and restricted areas (Wagait Shire Council, 2019).

5. Regulations and Accreditation of Assistance Animals

Currently in Australia the specific training of AAs is not regulated by Federal, State or Territory law. As per the *Disability Discrimination Act 1992* (Commonwealth), there are three pathways that an animal can qualify as an AA.

There are a number of training organisations, as mentioned in the State and Territory information and in Section 7, that have automatic approval for their trained assistance dogs. These organisations have a proven track record of training assistance dogs for people with a

disability and the dogs meet standards of hygiene and behaviour as outlined in the Disability Discrimination Act 1992.

Assistance Dogs International, as described in the report by Howell et al (2019), is an organisation committed to providing minimum standards of training, including public behaviour, and ethical treatment for assistance dogs. ADI members in Australia include: Assistance Dogs Australia, Australian Lions Hearing Dogs, Australian Support Dogs, Guide Dogs NSW/ACT, Guide Dogs Queensland, Guide Dogs SA/NT, Righteous Pups Australia, Royal Society for the Blind, Guide and Assistance Dog Service and Vision Australia Seeing Eye Dogs.

For States and Territories that offer an accreditation or certification pathway, including the Victorian Public Transport Pass, assistance dog trainers need to apply to the regulating authority detailing their experience in selecting and training AAs for people with a disability to be a recognised AA trainer. However there does not appear to be a defined 'standard' that trainers need to meet in order to achieve this recognition. Evidence that needs to be provided to state and territory bodies includes relevant qualifications, knowledge or experience in dog obedience training and what training methods will be used.

6. NDIA funding for Assistance Animals

A search of the *National Disability Insurance Scheme Act 2013* (Cth), *National Disability Insurance Scheme (Supports for Participants) Rules 2013* and NDIS Quality and Safeguards Commission does not provide information regarding what is required for an animal to be considered an AA with regards to NDIS funding.

Funding criteria for an AA is described in NDIS Our Guidelines (NDIS, 2021):

- The AA must be trained to do at least 3 specific tasks or behaviours that a participant needs but can't do because of their disability
- The AA must meet Reasonable and Necessary support
- The AA must meet the NDIS Rules for funding a support
- The provider needs to be an accredited AA provider; the provider may be registered with the NDIS Quality and Safeguards Commission or with the relevant state or territory authority for AAs
- The AA must pass a public access test so it can become qualified, which should be arranged by the training provider
- The AA must meet Commonwealth, state and territory laws

As detailed in Section 3, the criterion that an AA must be trained by an accredited organisation has been successfully challenged at the Administrative Appeals Tribunal by a participant with dog training experience and also through a legal case against Virgin Australia Airlines.

Therefore, while there are clear benefits of using an accredited assistance dog trainer it also provides a risk to the Agency if a suitable alternative is proposed and not funded.

The *Disability Discrimination Act 1992* (Commonwealth) states there are three pathways for an animal to be recognised as an AA. The State and Territory accreditation pathways are one approach to having a recognised and certified AA. However, as stated clearly by Western Australian and South Australian authorities, having state or territory accreditation does not provide additional protection for people with a disability and not having this accreditation does not remove public access rights for people with an AA. The benefit of having an AA either trained by a recognised training organisation or with state or territory accreditation is that it provides the AA user with a way to easily prove their AA is genuine when they are accessing public spaces.

Although not presented as an option in NDIS Our Guidelines, if a participant wanted to take the third pathway of AA recognition as per the *Disability Discrimination Act 1992* (Commonwealth) – training the animal themselves to meet their disability needs – they inadvertently increase their burden of proof that the AA is legitimate. As mentioned earlier in this report, it is not discrimination to request proof an AA is genuine and it is not discrimination to prevent an animal from accessing public spaces or public transport if proof cannot be provided.

For individuals who do not have a State or Territory accreditation card, or a training card from a recognised organisation, their proof may involve presenting a medical certificate as well as veterinarian certificate that the AA is genuine. As noted in RES 239 Animal Assisted Therapy and Assistance Animals, people with an AA are vulnerable to discrimination when in the community. Therefore, opting for a dog that can easily achieve State or Territory accreditation or that is trained through a recognised organisation may lessen negative interactions experienced by individuals with an AA while in public.

7. Organisations that train assistance animals

The following training organisations are listed on the Federal Government 'Disability Gateway' website as being recognised for their expertise in training assistance animals.

- Assistance Dogs Australia
- Aware Dogs Australia
- Guide Dogs Australia
- Guide Dogs SA/NT
- MindDog
- Royal Society for the Blind Guide and Assistance Dogs
    - Guide Dogs

* Autism Dogs
* Operation K9 for Veterans with PTSD

Additional organisations recognised for their expertise in training AAs are listed under each state and territory.

8. References

Agriculture Victoria. (2022). *Guide dogs, seeing eye dogs and assistance dogs.* Victorian Government. Accessed from https://agriculture.vic.gov.au/livestock-and-animals/animal-welfare-victoria/dogs/guide-dogs-seeing-eye-dogs-and-assistance-dogs

Companion Animals Act 1998 (NSW). Accessed from https://legislation.nsw.gov.au/view/whole/html/inforce/current/act-1998-087

Department of Premier and Cabinet. (n.d.). *Dog Control FAQ.* Accessed from https://www.dpac.tas.gov.au/divisions/local_government/legislation/current_legislation/dog_control/dog_control_faqs

Department of Local Government, Sport and Cultural Industries. (2021). *Applying for assistance dog approval.* Government of Western Australia. Accessed from https://www.dlgsc.wa.gov.au/local-government/community/cats-and-dogs/applying-for-assistance-dog-approval

Department of Seniors, Disability Services and ATSI Partnerships. (n.d.). *Frequently asked questions – businesses*. Accessed 28/4/22 from https://www.dsdsatsip.qld.gov.au/resources/dsdsatsip/disability/guide-hearing-assistance-dogs/facts-faqs-business.pdf

Department of Seniors, Disability Services and ATSI Partnerships. (2018). *Guide, hearing and assistance dogs*. Queensland Government. Accessed from https://www.qld.gov.au/disability/out-and-about/ghad

Department of Seniors, Disability Services and ATSI Partnerships. (n.d.). *Legislation and public access*. Accessed 28/4/22 from https://www.dsdsatsip.qld.gov.au/resources/dsdsatsip/disability/guide-hearing-assistance-dogs/facts-legislation-and-access.pdf

Disability Discrimination Act 1992 (Commonwealth). Accessed from https://www.legislation.gov.au/Details/C2022C00087

Disability Services. (2009). *Guide, hearing and assistance dogs legislation. Information for businesses.* Queensland Government. Accessed from https://www.qld.gov.au/__data/assets/pdf_file/0030/216687/ghadogs-businesses-booklet.pdf

Disability Services Act 1993 (NT). Accessed from https://legislation.nt.gov.au/en/Legislation/DISABILITY-SERVICES-ACT-1993

Dog Act 1976 (Western Australia).

Domestic Animals Act 2000 (ACT). Accessed from https://www.legislation.act.gov.au/DownloadFile/a/2000-86/current/DOCX/2000-86.DOCX

Domestic Animals Act 1994 (Vic). Accessed from http://www5.austlii.edu.au/au/legis/vic/consol_act/daa1994163/index.html#s7

Equal Opportunity Act 2010 (Vic). Accessed from https://content.legislation.vic.gov.au/sites/default/files/2022-03/10-16a025.docx

Guide Dogs and Hearing Dogs Act 1967 (Tas). Accessed from https://www.legislation.tas.gov.au/view/whole/html/inforce/current/act-1967-042

Guide, Hearing and Assistance Dogs Act 2009 (Qld). Accessed from https://www.legislation.qld.gov.au/view/pdf/2013-12-06/act-2009-004

Howell, T., Bennett, P., & Tepper, D. (2019). *Key terms for animals in disability assistance roles*. Department of Psychology and Counselling, La Trobe University. Access from https://www.ndis.gov.au/media/2542/download

Human Rights Commission. (2016). *Assistance animals and the Disability Discrimination Act 1992* (Cth). Accessed from https://humanrights.gov.au/our-work/disability-rights/projects/assistance-animals-and-disability-discrimination-act-1992-cth#:~:text=There%20is%20local%20government%20legislation%20providing%20for%20animals,dog%20meets%20certain%20standards%20of%20behaviour%20in%20public.?msclkid=ca60d9c9aafd11ec81bbb5ee89c69229

National Disability Insurance Scheme. (2021). *Assistance animals including guide dogs*. Accessed from https://ourguidelines.ndis.gov.au/media/1566/download?attachment

National Disability Insurance Scheme Act 2013 (Commonwealth) accessed from https://www.legislation.gov.au/Details/C2013A00020

National Disability Insurance Scheme (Supports for Participants) Rules 2013. Accessed from https://www.legislation.gov.au/Details/F2013L01063

National Disability Insurance Scheme Quality and Safeguards Commission. (n.d.). Accessed from https://www.ndiscommission.gov.au/

Office of Local Government. (2022). *Assistance Animals*. New South Wales Government. Accessed from https://www.olg.nsw.gov.au/public/dogs-cats/responsible-pet-ownership/assistance-animals/?msclkid=fa3e4b3cb0d511ecac933256283c0d0b

Public Transport Victoria. (2019). *Assistance Animal Pass*. Victorian Government. Accessed from https://www.ptv.vic.gov.au/assets/default-site/tickets/myki/concessions-and-free-travel/assistance-animal-pass/6c06e5093f/Assistance-Animal-Pass-Accessible-Version-Effective-November-2019.docx

Transport for NSW. (2021). *Assistance animal policy*. New South Wales Government. Accessed from https://transportnsw.info/document/5511/transport_for_nsw_assistance_animal_policy.pdf

Transport for NSW. (n.d.). *Apply for an assistance animal permit*. New South Wales Government. Accessed from https://transportnsw.info/tickets-opal/ticket-eligibility-concessions/people-with-disabilities/apply-for-assistance-animal

Wagait Shire Council. (2019). *Dog Management by-laws*. Accessed from https://legislation.nt.gov.au/api/sitecore/SubordinateLegislation/Word?id=5372B

9. Version control

Version	Amended by	Brief Description of Change	Status	Date
0.5	SJP131	Document created	Draft	28/4/22
0.9	MDN475	Minor Revision	Draft	04/05/22
1.0	SJP131	Final review	Cleared	5/5/22