

QUESTION



Should customized assistive technology for communication and to expand workplace opportunities (e.g. writing, speech, computer use, tablets, workplace design [adaptive seating and positioning], vision and hearing) vs. non-use be used for subjects with impaired communicating ability and work place difficulties who use digital and assistive technology with Friedreich ataxia?

POPULATION:	subjects with impaired communicating ability and work place difficulties who use digital and assistive technology with Friedreich ataxia
INTERVENTION:	customized assistive technology for communication and to expand workplace opportunities (e.g. writing, speech, computer use, tablets, workplace design [adaptive seating and positioning], vision and hearing)
COMPARISON:	non-use
MAIN OUTCOMES:	Independence in communication; Independence in communication; Quality of life; Quality of life; Posture; Occupational participation;

ASSESSMENT

Problem					
Is the problem a priority?					
JUDGEMENT	RESEARCH EVIDENCE			ADDITIONAL CONSIDERATIONS	
<ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Probably no <input checked="" type="radio"/> Probably yes <input type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 				<p>The Friedreich's ataxia Clinical Management Guideline Patient and Parent Advisory Panel were interviewed on the consequences, urgency and priority of digital and assistive technologies.</p> <p>4/6 indicated that the problem was serious, 2/6 indicated they didn't know if serious.</p> <p>2/6 indicated that the problem was urgent, 1/6 indicated probably urgent, 1/6 indicated probably not urgent, 2/6 indicated they didn't know if urgent.</p> <p>3/6 indicated that the problem was a priority, 1/6 indicated probably a priority, 2/6 indicated they didn't know if a priority. (Aug 2020)</p>	
Desirable Effects					
How substantial are the desirable anticipated effects?					
JUDGEMENT	RESEARCH EVIDENCE			ADDITIONAL CONSIDERATIONS	
<ul style="list-style-type: none"> <input type="radio"/> Trivial <input checked="" type="radio"/> Small <input type="radio"/> Moderate <input type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 					
	Outcomes	№ of	Certainty of	Relative	Anticipated absolute effects* (95% CI)

	participants (studies) Follow-up	the evidence (GRADE)	effect (95% CI)	Risk with non-use	Risk difference with Customized assistive technology for communication and to expand workplace opportunities (e.g. writing, speech, computer use, tablets, workplace design [adaptive seating and positioning], vision and hearing)
Independence in communication assessed with: ALS Functional Rating Scale - revised	27 (1 RCT) ¹	⊕○○○ Very low ^{a,b,c,d,e,f}	-		The impact of early introduction of assistive communication devices (ACDs) on quality of life were examined in 27 people with amyotrophic lateral sclerosis (ALS). Patients were followed for 7-10 months and assessed at baseline (T0), 3-4 months later (T1) and 7-10 months after entry (T2). Patients were randomised to early intervention (G1, n=15) or late intervention (G2, n=11) groups. Evaluation of bulbar function (ALSFRS-R-b score) decreased significantly over time. The decline was linear and showed no difference in percentage change between T0-T1 and T1-T2. There was no significant difference between the 2 patient groups in bulbar score decline. The higher the bulbar impairment (lower ALSFRS-R-b scores), the lower the self-perceived communication effectiveness index (CETI-m) for patients in G1 ($r = 0.419, p < 0.001$) and G2 ($r = 0.809, p < 0.001$). However, when considering data from patients in G1, after they started to use the ACD (T1 and T2), patients with lower bulbar functional scores did not necessarily have lower self-perceived communication ($r = 0.101, p = 0.629$). (Londral et al 2015).
Independence in communication assessed with: modified Communication Effectiveness	27 (1 RCT) ¹	⊕○○○ Very low ^{a,b,c,d,e,f}	-		The impact of early introduction of assistive communication devices (ACDs) on quality of life were examined in 27 people with amyotrophic lateral sclerosis (ALS). Patients were followed for 7-10 months and assessed at baseline (T0), 3-4 months later (T1) and

Index				<p>7-10 months after entry (T2). Patients were randomised to early intervention (G1, n=15) or late intervention (G2, n=11) groups. The higher the bulbar impairment (lower ALSFRS-R-b scores), the lower the self-perceived communication effectiveness index (CETI-m) for patients in G1 ($r = 0.419, p < 0.001$) and G2 ($r = 0.809, p < 0.001$). However, when considering data from patients in G1, after they started to use the ACD (T1 and T2), patients with lower bulbar functional scores did not necessarily have lower self-perceived communication ($r = 0.101, p = 0.629$). Patients with higher scores in self-perceived communication effectiveness had higher QoL, both in total score ($r = 0.268, p = 0.027$) and in the psychological symptoms domain ($r = 0.265, p = 0.029$). (Londral et al 2015).</p>
Quality of life assessed with: World Health Organization Quality of Life	27 (1 RCT) ¹	 Very low ^{a,b,c,d,e,f}	-	<p>The impact of early introduction of assistive communication devices (ACDs) on quality of life were examined in 27 people with amyotrophic lateral sclerosis (ALS). Patients were followed for 7-10 months and assessed at baseline (T0), 3-4 months later (T1) and 7-10 months after entry (T2). Patients were randomised to early intervention (G1, n=15) or late intervention (G2, n=11) groups. The WHOQoL-BREF was completed by caregivers of the patients. The mean scores of the WHOQoL-BREF showed a decrease ($p < 0.05$) in all domains, from T0 to T2, except for the social relations domain ($p = 0.749$). (Londral et al 2015).</p>
Quality of life assessed with: McGill Quality of Life	27 (1 RCT) ¹	 Very low ^{a,b,c,d,e,f}	-	<p>The impact of early introduction of assistive communication devices (ACDs) on quality of life were examined in 27 people with amyotrophic lateral sclerosis (ALS). Patients were followed for 7-10 months and assessed at baseline (T0), 3-4 months later (T1) and 7-10 months after entry (T2). Patients</p>

				<p>were randomised to early intervention (G1, n=15) or late intervention (G2, n=11) groups. Mean values calculated for all patients (through MQoL) showed a decrease in total, physical, and existential domains of QoL ($p < 0.05$). Single-index score, psychological symptoms, and support domains did not change with time ($p > 0.05$). In descriptive parts of the MQoL (physical symptoms and part D), 23 patients (88.5%) referred in at least 1 assessment to speech problems or difficulty being understood by others as negative factors in QoL; 2 patients in G1 referred to communication device as having a positive impact in QoL. Patients with early intervention with their ACD had higher MQoL scores than the other patients, particularly for the existential well-being domain at T1 ($p=0.045$) and the psychological symptoms domain, both at T1 ($p=0.047$) and T2 ($p=0.032$). (Londral et al 2015).</p>
Posture - not measured	-	-	-	-
Occupational participation assessed with: ALS Functional Rating Scale—revised	27 (1 RCT) ¹	⊕○○○ Very low ^{a,b,c,d,e,f}	-	<p>The impact of early introduction of assistive communication devices (ACDs) on quality of life were examined in 27 people with amyotrophic lateral sclerosis (ALS). Patients were followed for 7-10 months and assessed at baseline (T0), 3-4 months later (T1) and 7-10 months after entry (T2). Patients were randomised to early intervention (G1, n=15) or late intervention (G2, n=11) groups. Evaluation of bulbar function (ALSFERS-R-b score) decreased significantly over time. The decline was linear and showed no difference in percentage change between T0–T1 and T1–T2. There was no significant difference between the 2 patient groups in bulbar score decline. The higher the bulbar impairment (lower Δ ALSFERS-R-b scores) the lower the self-</p>

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Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS												
<ul style="list-style-type: none"> ○ Large ○ Moderate ○ Small ○ Trivial ○ Varies ● Don't know 	<table border="1" data-bbox="520 1089 1417 1455"> <thead> <tr> <th data-bbox="520 1089 690 1455">Outcomes</th> <th data-bbox="690 1089 816 1455">No of participants (studies) Follow-up</th> <th data-bbox="816 1089 957 1455">Certainty of the evidence (GRADE)</th> <th data-bbox="957 1089 1050 1455">Relative effect (95% CI)</th> <th colspan="2" data-bbox="1050 1089 1417 1130">Anticipated absolute effects* (95% CI)</th> </tr> </thead> <tbody> <tr> <td data-bbox="520 1130 690 1455"></td> <td data-bbox="690 1130 816 1455"></td> <td data-bbox="816 1130 957 1455"></td> <td data-bbox="957 1130 1050 1455"></td> <td data-bbox="1050 1130 1121 1455">Risk with non-use</td> <td data-bbox="1121 1130 1417 1455">Risk difference with Customized assistive technology for communication and to expand workplace opportunities (e.g. writing, speech, computer use, tablets, workplace design [adaptive seating and positioning], vision and hearing)</td> </tr> </tbody> </table>	Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)						Risk with non-use	Risk difference with Customized assistive technology for communication and to expand workplace opportunities (e.g. writing, speech, computer use, tablets, workplace design [adaptive seating and positioning], vision and hearing)	<p>No undesirable effects have been reported</p>
Outcomes	No of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)										
				Risk with non-use	Risk difference with Customized assistive technology for communication and to expand workplace opportunities (e.g. writing, speech, computer use, tablets, workplace design [adaptive seating and positioning], vision and hearing)									

	<p>Independence in communication assessed with: ALS Functional Rating Scale - revised</p>	<p>27 (1 RCT)¹</p>	<p>⊕○○○ Very low^{a,b,c,d,e,f}</p>	<p>-</p>	<p>The impact of early introduction of assistive communication devices (ACDs) on quality of life were examined in 27 people with amyotrophic lateral sclerosis (ALS). Patients were followed for 7-10 months and assessed at baseline (T0), 3-4 months later (T1) and 7-10 months after entry (T2). Patients were randomised to early intervention (G1, n=15) or late intervention (G2, n=11) groups. Evaluation of bulbar function (ALSFERS-R-b score) decreased significantly over time. The decline was linear and showed no difference in percentage change between T0–T1 and T1–T2. There was no significant difference between the 2 patient groups in bulbar score decline. The higher the bulbar impairment (lower ALSFRS-R-b scores), the lower the self-perceived communication effectiveness index (CETI-m) for patients in G1 ($r = 0.419, p < 0.001$) and G2 ($r = 0.809, p < 0.001$). However, when considering data from patients in G1, after they started to use the ACD (T1 and T2), patients with lower bulbar functional scores did not necessarily have lower self-perceived communication ($r = 0.101, p = 0.629$). (Londral et al 2015).</p>	
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Posture - not measured	-	-	-	-
Occupational participation assessed with: ALS Functional Rating Scale—revised	27 (1 RCT) ¹	⊕○○○ Very low ^{a,b,c,d,e,f}	-	<p>The impact of early introduction of assistive communication devices (ACDs) on quality of life were examined in 27 people with amyotrophic lateral sclerosis (ALS). Patients were followed for 7-10 months and assessed at baseline (T0), 3-4 months later (T1) and 7-10 months after entry (T2). Patients were randomised to early intervention (G1, n=15) or late intervention (G2, n=11) groups. Evaluation of bulbar function (ALSFERS-R-b score) decreased significantly over time. The decline was linear and showed no difference in percentage change between T0–T1 and T1–T2. There was no significant difference between the 2 patient groups in bulbar score decline. The higher the bulbar impairment (lower ALSFRS-R-b scores), the lower the self-perceived communication effectiveness index (CETI-m) for patients in G1 ($r = 0.419, p < 0.001$) and G2 ($r = 0.809, p < 0.001$). However, when considering data from patients in G1, after they started to use the ACD (T1 and T2), patients with lower bulbar functional scores did not necessarily have lower self-perceived communication ($r = 0.101, p =$</p>

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Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ● Very low ○ Low ○ Moderate ○ High ○ No included studies 	<p data-bbox="520 764 1140 786">There is very low certainty of evidence as per the Evidence Profile table.</p>	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS						
<ul style="list-style-type: none"> ○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability 	<table border="1" data-bbox="520 1313 1417 1503"> <thead> <tr> <th data-bbox="520 1313 1058 1398">Outcomes</th> <th data-bbox="1058 1313 1192 1398">Importance</th> <th data-bbox="1192 1313 1417 1398">Certainty of the evidence (GRADE)</th> </tr> </thead> <tbody> <tr> <td data-bbox="520 1398 1058 1503">Independence in communication assessed with: ALS Functional Rating Scale - revised</td> <td data-bbox="1058 1398 1192 1503">IMPORTANT^a</td> <td data-bbox="1192 1398 1417 1503">  VERY LOW^{b,c,d,e,f,g} </td> </tr> </tbody> </table>	Outcomes	Importance	Certainty of the evidence (GRADE)	Independence in communication assessed with: ALS Functional Rating Scale - revised	IMPORTANT ^a	 VERY LOW ^{b,c,d,e,f,g}	
Outcomes	Importance	Certainty of the evidence (GRADE)						
Independence in communication assessed with: ALS Functional Rating Scale - revised	IMPORTANT ^a	 VERY LOW ^{b,c,d,e,f,g}						

Independence in communication assessed with: modified Communication Effectiveness Index	IMPORTANT ^a	⊕○○○ VERY LOW ^{b,c,d,e,f,g}
Quality of life assessed with: World Health Organization Quality of Life		⊕○○○ VERY LOW ^{b,c,d,e,f,g}
Quality of life assessed with: McGill Quality of Life	IMPORTANT ^h	⊕○○○ VERY LOW ^{b,c,d,e,f,g}
Posture - not measured	IMPORTANT ⁱ	-
Occupational participation assessed with: ALS Functional Rating Scale—revised	CRITICAL ^j	⊕○○○ VERY LOW ^{b,c,d,e,f,g}

- a. Identified as low importance (1/5), important (3/5), critical (1/5) by people with FA and critical by expert authors on this topic
- b. Participants with a diagnosis of Amyotrophic lateral sclerosis (not FRDA).
- c. Single study with small sample size.
- d. Confidence intervals not reported.
- e. Small sample size.
- f. Investigators not blinded to allocation
- g. Withdrawal (n=3)
- h. Identified as important (3/5), critical (2/5) by people with FA and important by expert authors on this topic
- i. Identified as important (4/5), critical (1/5) by people with FA and important by expert authors on this topic
- j. Identified as low importance (1/5), important (2/5), critical (2/5) by people with FA and critical by expert authors on this topic

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT

RESEARCH EVIDENCE

ADDITIONAL CONSIDERATIONS

<ul style="list-style-type: none"> ○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know 	<p>Expert opinion based on 4 responders suggests that all agree ACD can benefit independence in communication, QOL and occupational participation.</p>	<p>A survey designed to systematically collect expert-based opinions from clinicians involved in developing the recommendations for this topic and providing clinical care for individuals with Friedreich ataxia, was conducted. Clinical experts from Australia, Europe, UK, South America, Canada and the USA were asked to consider the harms/benefits of Customized assistive technology for communication and to expand workplace opportunities (e.g. writing, speech, computer use, tablets, workplace design [adaptive seating and positioning], vision and hearing) as a management strategy for individuals with im.</p> <p>Reflecting on the impact of Customized assistive technology for communication and to expand workplace opportunities (e.g. writing, speech, computer use, tablets, workplace design [adaptive seating and positioning], vision and hearing) on <u>Independence in communication</u>, 100% (4/4) clinical experts reported a benefit (large, moderate or small), and 0% (0/4) reported observing a harm (large, moderate or small).</p> <p>Reflecting on the impact on <u>Quality of life</u>, 100% (4/4) clinical experts reported a benefit.</p> <p>Reflecting on the impact on <u>Posture</u>, 75% (3/4) clinical experts reported a benefit, 25% (1/4) reported no effect.</p> <p>Reflecting on the impact on <u>Occupational participation</u>, 100% (4/4) clinical experts reported a benefit.</p>
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Acceptability
Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
<ul style="list-style-type: none"> ○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know 	<p>No published evidence.</p>	<p>The Friedreich's ataxia Clinical Management Guideline Patient and Parent Advisory Panel were asked if customized assistive technology for communication and expanding workplace opportunities for people with impaired communicating ability and workplace difficulties were acceptable (weighing up the balance between benefits, harms and costs).</p> <p>4/5 indicated that the intervention was acceptable, 1/5 indicated probably acceptable. (Aug 2020).</p>

SUMMARY OF JUDGEMENTS

JUDGEMENT

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ●	Strong recommendation for the intervention ○
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CONCLUSIONS

Recommendation

For individuals with Friedreich ataxia with impaired communication and workplace difficulties, we suggest the use of customized assistive technology for communication and the workplace (e.g., writing, speech, computer use, tablets, workplace design [adaptive seating and positioning], vision and hearing) to enhance independence in communication, improve quality of life and increase occupational participation.

Justification

Despite the low level of evidence in like conditions, expert clinicians who provide clinical care for individuals with Friedreich ataxia agree that customized assistive technology for communication can benefit independence in communication, quality of life and occupational participation in individuals with Friedreich ataxia, particularly in the later stage of the disease.

Subgroup considerations

The provision of customized assistive technology is particularly relevant to individuals with advanced Friedreich ataxia who may have concurrent issues related to upper limb ataxia, visual difficulties and eye movement problems.

Research priorities

Key research priorities in this area include identifying and evaluating the most appropriate customized assistive technology for individuals with Friedreich ataxia and measuring efficacy against effects on independence in communication; quality of life and occupational participation.