

QUESTION

Should lifestyle changes (exercise, diet, social activities) vs. none or other antidepressant treatment be used for depressed patients with Friedreich ataxia?

POPULATION:	depressed patients with Friedreich ataxia
INTERVENTION:	lifestyle changes (exercise, diet, social activities)
COMPARISON:	none or other antidepressant treatment
MAIN OUTCOMES:	Less depression; Less depression; Better coping/ outlook; Reduced vegetative symptoms; Better coping/outlook; QOL; QOL;

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 type="radio"/> Probably yes <input checked="" type="radio"/> Yes <input type="radio"/> Varies <input type="radio"/> Don't know 	<p>In a cohort of 62 individuals with FA the mean BDI score was 15.32 (SD=10.33). Minimal depressive symptoms were observed in 50% of participants, 23% of participants scored in the “mild” range, 23% had moderate depressive symptoms, and 5% scored in the “severe” range (Perez-Flores et al 2020). In a cohort of 57 adults with FA the mean BDI score for FRDA patients was 13.62 (SD = 9.52) which is significantly higher than the mean score in the general population ($t(56) = 3.15, p < .01$), according to populations norms (Neito et al 2018),</p> <p>Depression varies: one study using the Beck Depression Inventory (BDI-II) showed the following frequencies for each level of depression: 0–9 (score normal) 21/33 patients, 63.6%; 10–18: mild depression 6/33 patients, 18.2%; 19–29: moderate depression 5/33 patients, 15.1%; 30–63: severe depression 1/33 patient, 3% (Alexandra Durr, personal communication, 2021).</p>	<p>The Friedreich’s ataxia Clinical Management Guideline Patient and Parent Advisory Panel were interviewed on the consequences, urgency and priority of depression.</p> <p>5/6 indicated that the problem was serious, 1/6 indicated they didn’t know if serious.</p> <p>4/6 indicated that the problem was urgent, 1/6 indicated probably urgent, 1/6 indicated probably not urgent.</p> <p>4/6 indicated that the problem was a priority, 2/6 indicated probably 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 type="radio"/> Small <input type="radio"/> Moderate <input checked="" type="radio"/> Large <input type="radio"/> Varies <input type="radio"/> Don't know 	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Outcomes</th> <th style="width: 10%;">№ of</th> <th style="width: 10%;">Certainty of</th> <th style="width: 10%;">Relative</th> <th style="width: 50%;">Anticipated absolute effects* (95% CI)</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table>	Outcomes	№ of	Certainty of	Relative	Anticipated absolute effects* (95% CI)						<p>The expert authors consider the issue of social isolation in FA to be considerable and contributes to depression. Activity counteracts the effects of depression. Main benefit of activity is in mood and depression. Importance of driving to facilitate social interaction. Young people are resistant to interacting with peers because they are different which contributes to social isolation. Activity is of great benefit; however, accessibility is an important consideration. Importance of manipulating lifestyle habits to ensure participation; maintain circle of friends.</p>
Outcomes	№ of	Certainty of	Relative	Anticipated absolute effects* (95% CI)								

	participants (studies) Follow up	the evidence (GRADE)	effect (95% CI)	Risk with none or other antidepressant treatment	Risk difference with lifestyle changes (exercise, diet, social activities)
Less depression assessed with: Profile of Mood States	0 (1 observational study) ¹	⊕○○○ VERY LOW ^{a,b,c,d,e,f}	-	Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2 competitive Boccia (IC: independent competitive, and NIC: nonindependent competitive), recreational Boccia and control groups. The participants were followed for 4 months between pre and post tests and all underwent an individualised rehabilitation program. A one-way ANOVA and MANOVA were used to examine the effect of training on scores of psychosocial variables with one and multiple levels, respectively. There were no between-group differences in the POMS (p ≥ 0.05).	
Less depression assessed with: General Health Questionnaire-28	0 (1 observational study) ¹	⊕○○○ VERY LOW ^{a,b,c,d,e,f}	-	Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2 competitive Boccia (IC: independent competitive, and NIC: nonindependent competitive), recreational Boccia and control groups. The participants were followed for 4 months between pre and post tests and all underwent an individualised rehabilitation program. A one-way ANOVA and MANOVA were used to examine the effect of training on scores of psychosocial variables with one and multiple levels, respectively. There were no between-group differences in the GHQ-28.	
Better coping/ outlook assessed with: Rosenberg Self-Esteem	0 (1 observational study) ¹	⊕○○○ VERY LOW ^{a,b,c,d,e,f}	-	Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2 competitive Boccia (IC: independent	

Negative impact of FA on pursuing a career or schooling. Young people having to return to living with parents as they are providing carer support. Negative impact on self-esteem. Desirable effect of lifestyle on autonomy and mental health.

Barriers to activity are significant.

				<p>competitive, and NIC: nonindependent competitive), recreational Boccia and control groups. The participants were followed for 4 months between pre and post tests and all underwent an individualised rehabilitation program. A one-way ANOVA and MANOVA were used to examine the effect of training on scores of psychosocial variables with one and multiple levels, respectively. There were no between-group differences in the Rosenberg Self-Esteem. In within group analysis, the NIC group presented improvements on the Rosenberg Self-Esteem: pretest mean scores 22.42, SD 7.52 to posttest mean scores 26.85, SD 1.38 ($p < 0.05$).</p>
Reduced vegetative symptoms assessed with: Profile of Mood States	0 (1 observational study) ¹	 VERY LOW ^{a,b,c,d,e,f}	-	<p>Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2 competitive Boccia (IC: independent competitive, and NIC: nonindependent competitive), recreational Boccia and control groups. The participants were followed for 4 months between pre and post tests and all underwent an individualised rehabilitation program. A one-way ANOVA and MANOVA were used to examine the effect of training on scores of psychosocial variables with one and multiple levels, respectively. There were no between-group differences in the POMS ($p \geq 0.05$).</p>
Better coping/outlook assessed with: State-Trait Anxiety Inventory	0 (1 observational study) ¹	 VERY LOW ^{a,b,c,d,e,f}	-	<p>Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2 competitive Boccia (IC: independent competitive, and NIC: nonindependent competitive), recreational Boccia and control groups. The participants were followed for 4 months between pre and post tests and all underwent an individualised rehabilitation program. A one-way ANOVA and MANOVA were</p>



				used to examine the effect of training on scores of psychosocial variables with one and multiple levels, respectively. There were no between-group differences in the STAI ($p \geq 0.05$).
QOL assessed with: World Health Organization Quality of Life-BREF assessment	0 (1 observational study) ¹	⊕○○○ VERY LOW ^{a,b,c,d,e,f}	-	Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2 competitive Boccia (IC: independent competitive, and NIC: nonindependent competitive), recreational Boccia and control groups. The participants were followed for 4 months between pre and post tests and all underwent an individualised rehabilitation program. A one-way ANOVA and MANOVA were used to examine the effect of training on scores of psychosocial variables with one and multiple levels, respectively. Change in psychosocial parameters was not significantly influenced by the study group ($p \geq 0.05$). The four groups improved significantly from pre- to posttest in WHOQOL-BREF Physical: IC group (pretest mean 16.11, SD 5.25 to mean posttest 28.77 SD 3.15), NIC group (pretest mean 17.00, SD 6.65 to posttest mean 30.28, SD 12.60), recreational group (pretest mean 12.92, SD 5.45 to posttest mean 24.50, SD 6.69), control group (pretest mean 10.92, SD 4.57 to posttest mean 24.92, SD 5.34). In addition, the control group also showed improvements in WHOQOL-BREF Psychological (pretest mean 11.69, SD 5.60 to posttest mean 17.30, SD 7.36).
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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 1117 1415 1490"> <thead> <tr> <th data-bbox="520 1117 682 1367" rowspan="2">Outcomes</th> <th data-bbox="682 1117 823 1367" rowspan="2">No of participants (studies) Follow up</th> <th data-bbox="823 1117 963 1367" rowspan="2">Certainty of the evidence (GRADE)</th> <th data-bbox="963 1117 1058 1367" rowspan="2">Relative effect (95% CI)</th> <th colspan="2" data-bbox="1058 1117 1415 1182">Anticipated absolute effects* (95% CI)</th> </tr> <tr> <th data-bbox="1058 1182 1249 1367">Risk with none or other antidepressant treatment</th> <th data-bbox="1249 1182 1415 1367">Risk difference with lifestyle changes (exercise, diet, social activities)</th> </tr> </thead> <tbody> <tr> <td data-bbox="520 1367 682 1490">Less depression assessed with: Profile of Mood</td> <td data-bbox="682 1367 823 1490">0 (1 observational)</td> <td data-bbox="823 1367 963 1490">⊕○○○ VERY LOW^{a,b,c,d,e,f}</td> <td data-bbox="963 1367 1058 1490">-</td> <td colspan="2" data-bbox="1058 1367 1415 1490">Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2</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 none or other antidepressant treatment	Risk difference with lifestyle changes (exercise, diet, social activities)	Less depression assessed with: Profile of Mood	0 (1 observational)	⊕○○○ VERY LOW ^{a,b,c,d,e,f}	-	Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2		<p>Motivation to make lifestyle changes can be difficult if the person is depressed.</p>
Outcomes	No of participants (studies) Follow up					Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)								
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<p>Better coping/outlook assessed with: State-Trait Anxiety Inventory</p>	<p>0 (1 observational study)¹</p>	<p>⊕○○○ VERY LOW^{a,b,c,d,e,f}</p>	-	<p>Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2 competitive Boccia (IC: independent competitive, and NIC: nonindependent competitive), recreational Boccia and control groups. The participants were followed for 4 months between pre and post tests and all underwent an individualised rehabilitation program. A one-way ANOVA and MANOVA were used to examine the effect of training on scores of psychosocial variables with one and multiple levels, respectively. There were no between-group differences in the STAI ($p \geq 0.05$).</p>
<p>QOL assessed with: World Health Organization</p>	<p>0 (1 observational study)¹</p>	<p>⊕○○○ VERY LOW^{a,b,c,d,e,f}</p>	-	<p>Participants with cerebral palsy (n=23), traumatic brain injury (n=6), multiple sclerosis (n=7) and Friedreich ataxia (n=7) were divided into 4 cohorts: 2</p>

Quality of Life-BREF assessment				<p>competitive Boccia (IC: independent competitive, and NIC: nonindependent competitive), recreational Boccia and control groups. The participants were followed for 4 months between pre and post tests and all underwent an individualised rehabilitation program. A one-way ANOVA and MANOVA were used to examine the effect of training on scores of psychosocial variables with one and multiple levels, respectively. Change in psychosocial parameters was not significantly influenced by the study group ($p \geq 0.05$). The four groups improved significantly from pre- to posttest in WHOQOL-BREF Physical: IC group (pretest mean 16.11, SD 5.25 to mean posttest 28.77 SD 3.15), NIC group (pretest mean 17.00, SD 6.65 to posttest mean 30.28, SD 12.60), recreational group (pretest mean 12.92, SD 5.45 to posttest mean 24.50, SD 6.69), control group (pretest mean 10.92, SD 4.57 to posttest mean 24.92, SD 5.34). In addition, the control group also showed improvements in WHOQOL-BREF Psychological (pretest mean 11.69, SD 5.60 to posttest mean 17.30, SD 7.36).</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>Very low certainty of evidence as per the evidence profile table.</p>	<p>Expert opinion and limited research in like diseases indicates there may be some benefit of exercise.</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" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Outcomes</th> <th style="width: 20%;">Importance</th> <th style="width: 30%;">Certainty of the evidence (GRADE)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Less depression assessed with: Profile of Mood States</td> <td style="text-align: center;">IMPORTANT^a</td> <td style="text-align: center;"> ⊕○○○ VERY LOW^{b,c,d,e,f,g} </td> </tr> </tbody> </table>	Outcomes	Importance	Certainty of the evidence (GRADE)	Less depression assessed with: Profile of Mood States	IMPORTANT ^a	⊕○○○ VERY LOW ^{b,c,d,e,f,g}	<p>In some people, depression can play a protective role because it enables a person to stay where they are at – some may prefer the comfort of where they are at, even though they are depressed, and may not seek treatment.</p>
Outcomes	Importance	Certainty of the evidence (GRADE)						
Less depression assessed with: Profile of Mood States	IMPORTANT ^a	⊕○○○ VERY LOW ^{b,c,d,e,f,g}						

Less depression assessed with: General Health Questionnaire-28	IMPORTANT ^a	⊕○○○ VERY LOW ^{b,c,d,e,f,g}
Better coping/ outlook assessed with: Rosenberg Self-Esteem	IMPORTANT ^a	⊕○○○ VERY LOW ^{b,c,d,e,f,g}
Reduced vegetative symptoms assessed with: Profile of Mood States	IMPORTANT ^h	⊕○○○ VERY LOW ^{b,c,d,e,f,g}
Better coping/outlook assessed with: State-Trait Anxiety Inventory	IMPORTANT ^a	⊕○○○ VERY LOW ^{b,c,d,e,f,g}
QOL assessed with: World Health Organization Quality of Life-BREF assessment	CRITICAL ⁱ	⊕○○○ VERY LOW ^{b,c,d,e,f,g}
QOL assessed with: General Health Questionnaire-28	CRITICAL ⁱ	⊕○○○ VERY LOW ^{b,c,d,e,f,g}

- a. Identified as low importance (1/6), important (3/6), critical (2/6) by people with FA and important by expert authors on this topic
- b. Participants with a diagnosis of FRDA n=7/43
- c. Only single study published.
- d. Confidence Intervals not reported
- e. Small sample size in each group (ranging from n=7 to n=14)
- f. Lack of allocation concealment and unclear about why participants were allocated to specific groups.
- g. Recruitment bias (all from Spanish State Referral Centre).
- h. Identified as low importance (2/5), important (2/5), critical (1/5) by people with FA and important by expert authors on this topic
- i. Identified as important (3/6), critical (3/6) by people with FA and important 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 		
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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 	No published evidence.	<p>The Friedreich's ataxia Clinical Management Guideline Patient and Parent Advisory Panel were asked if lifestyle changes for people with depression was acceptable (weighing up the balance between benefits, harms and costs).</p> <p>3/4 indicated that the intervention was acceptable, 1/4 indicated probably acceptable. (Aug 2020).</p> <p>Patients who are comfortable in their depression may not find the intervention acceptable</p> <p>Accessibility issue?</p>

SUMMARY OF JUDGEMENTS

	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			

JUDGEMENT							
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 <input type="radio"/>	Conditional recommendation against the intervention <input type="radio"/>	Conditional recommendation for either the intervention or the comparison <input type="radio"/>	Conditional recommendation for the intervention <input type="radio"/>	Strong recommendation for the intervention <input checked="" type="radio"/>
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CONCLUSIONS

Recommendation

We recommend lifestyle changes (exercise, diet, social activities) either prior to or in conjunction with other interventions, including antidepressants, for individuals with Friedreich ataxia who have symptoms of depression.

Justification

Lifestyle changes may have a positive impact on depression. However, the use of antidepressants may assist in facilitating participation if depression is associated with lack of motivation. Therefore, lifestyle changes may be used in conjunction with other treatments, particularly medication. There may be significant barriers to participation related to FRDA that would need to be addressed to enable lifestyle changes.

Subgroup considerations

This recommendation is for individuals with Friedreich ataxia and depression. Consideration should be given to the stage of Friedreich ataxia, the age of the person, and the level of depression (mild vs severe). Suicidal or more severely depressed individuals with FRDA may need more targeted therapy.

Research priorities

Studies of desirable effects of lifestyle changes on autonomy and mental health.

Autonomy and independence important in lifestyle. Research on impact of having to live with parents and need to seek independent accommodation.

References

Nieto A, Hernández-Torres A, Pérez-Flores J, Montón F. Depressive symptoms in Friedreich ataxia. *Int J Clin Health Psychol*. 2018;18(1):18-26.

Pérez-Flores J, Hernández-Torres A, Montón F, et al. Health-related quality of life and depressive symptoms in Friedreich ataxia. *Qual Life Res* 2020;29(2):413–420.