

Effects of music interventions on depressive symptoms in care home residents across countries: The multinational MIDDEL trial

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Music interventions for dementia and depression in elderly care (MIDDEL)

- Aims:
 - Determine the effectiveness of group music therapy [GMT] and/or recreational choir singing [RCS] for reducing depression symptoms (and other outcomes) in people living with dementia
 - Examine heterogeneity of treatment effects across subgroups
- Multinational cluster-randomised trial
 - 1000 residents in 100 care home units
 - Australia 2018-2021 (NHMRC)
 - Norway, Germany, Netherlands, Türkiye, UK 2020-2023 (JPND)



Australia

- 318 residents
- Clear, lasting, clinically relevant effects of RCS:
 - 3 months (end of biweekly RCS)
 - 6 months (end of RCS, primary)
 - 12 months
- Some effects (secondary outcomes) of GMT
- Interpretation: inclusive, structured, behaviour activation, less cognitive load, fun

Clinical effectiveness of music interventions for dementia and depression in elderly care (MIDDEL): Australian cohort of an international pragmatic cluster-randomised controlled trial

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Summary

Background Dementia and depression are highly prevalent and comorbid conditions among older adults living in care homes and are associated with individual distress and rising societal costs. Effective, scalable, and feasible interventions are needed. Music interventions have shown promising effects, but the current evidence base is inconclusive. The present study aimed to determine the effectiveness of two different music interventions on the depressive symptoms of people with dementia living in residential aged care.

Methods We implemented a 2×2 factorial cluster-randomised controlled trial to determine whether **group music therapy (GMT)** is more effective than no GMT with standard care, or **recreational choir singing (RCS)** is more effective than no RCS with standard care, for reducing depressive symptoms and other secondary outcomes in people with dementia with mild to severe depressive symptoms living in residential aged care. Care home units with at least ten residents were allocated to GMT, RCS, GMT plus RCS, or standard care, using a computer-generated list with block randomisation (block size four). The protocolised interventions were delivered by music therapists (GMT) and community musicians (RCS). The primary outcome was **Montgomery-Åsberg Depression Rating Scale** score at 6 months, assessed by a masked assessor and analysed on an intention-to-treat basis using linear mixed-effects models, which examined the effects of GMT versus no-GMT and RCS versus no-RCS, as well as interaction effects of GMT and RCS. We report on the Australian cohort of an international trial. This trial is registered with ClinicalTrials.gov, NCT03496675, and anzctr.org.au, ACTRN12618000156280.

Findings Between June 15, 2018, and Feb 18, 2020, we approached 12 RAC facilities with 26 eligible care home units and, excluding six units who could not be enrolled due to COVID-19 lockdowns, we screened 818 residents. **Between July 18, 2018, and Nov 26, 2019, 20 care home units were randomised (318 residents).** Recruitment ceased on March 17, 2020, due to COVID-19. The primary endpoint, available from 20 care home units (214 residents), suggested **beneficial effects of RCS (mean difference −4.25, 95% CI −7.89 to −0.62; p=0.0221) but not GMT (mean difference −0.44, −4.32 to 3.43; p=0.8224).** No related serious adverse events occurred.

Interpretation Our study supports implementing **recreational choir singing as a clinically relevant therapeutic intervention in reducing depressive symptoms for people with dementia in the Australian care home context.**

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This online publication has been corrected. The corrected version first appeared at [thelancet.com/healthy-longevity](https://www.thelancet.com/healthy-longevity) on October 3, 2022

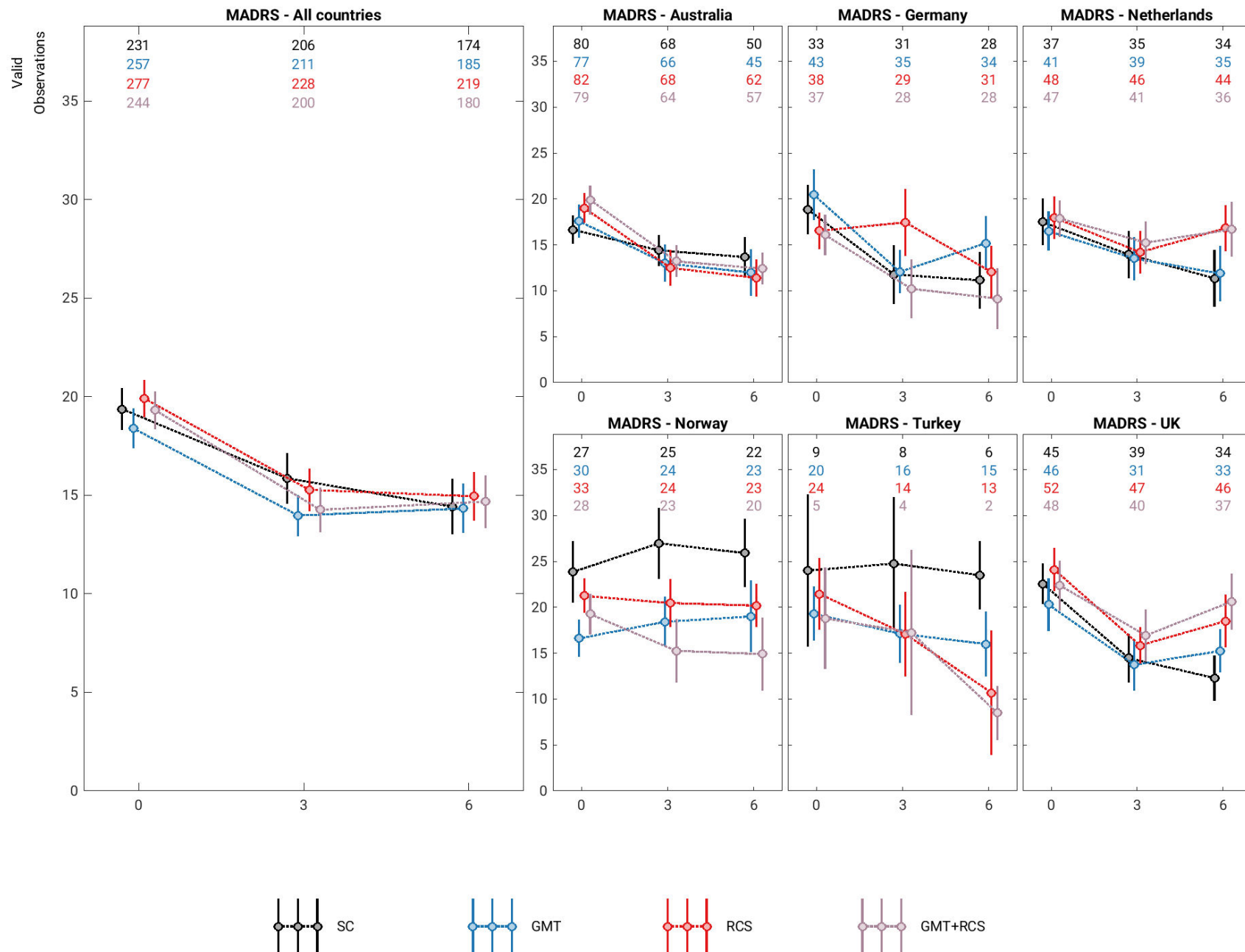
See [Comment](#) page e124

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All countries

- 1021 residents
- Intention-to-treat: No clear effects of RCS or GMT on primary endpoint
- Different patterns in each country

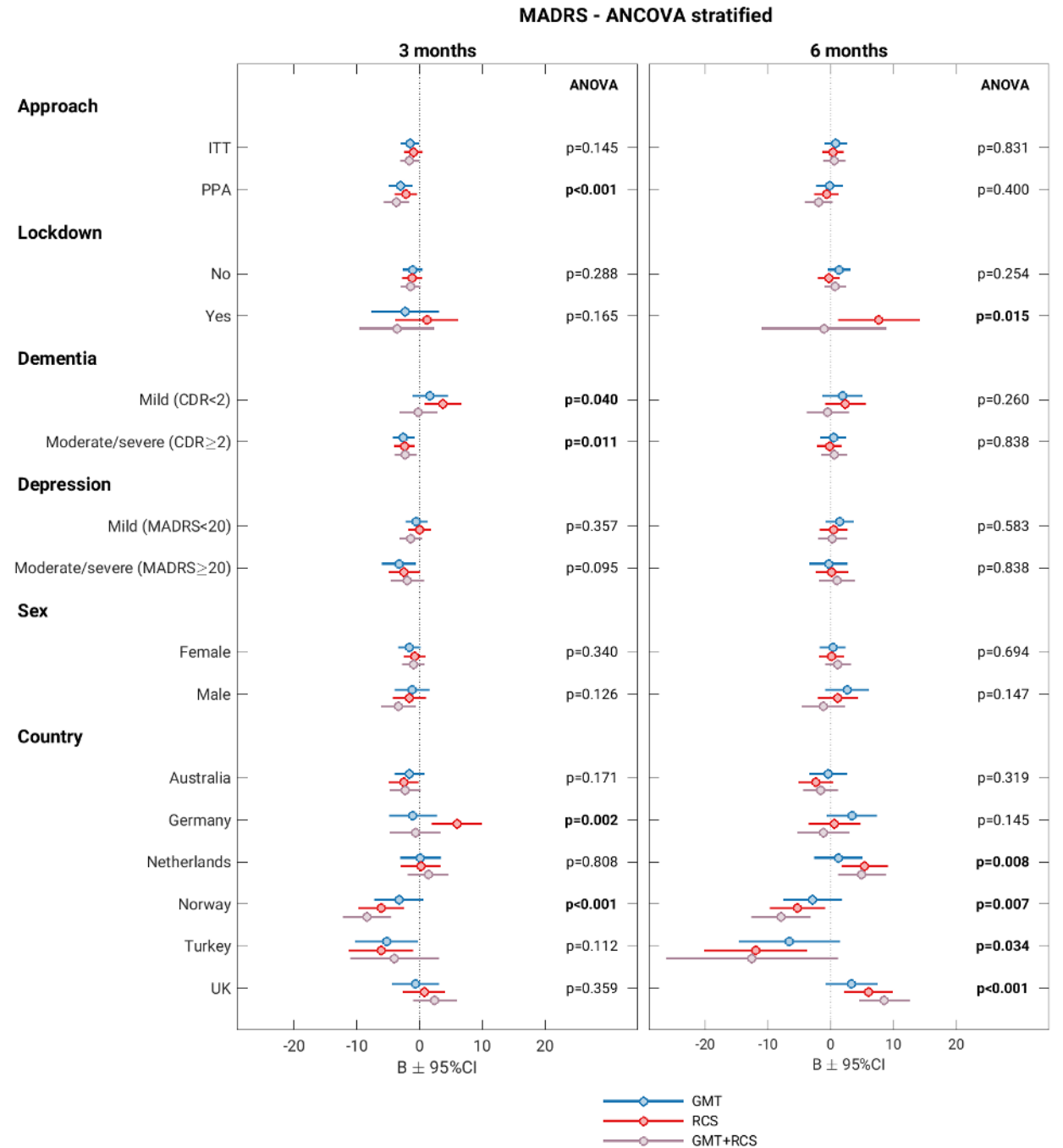


Sveinsdottir et al.,
in preparation

Clinical predictors

- Per-protocol sample ($\geq 50\%$ of sessions)
- Dementia (moderate to severe)
- **Country**

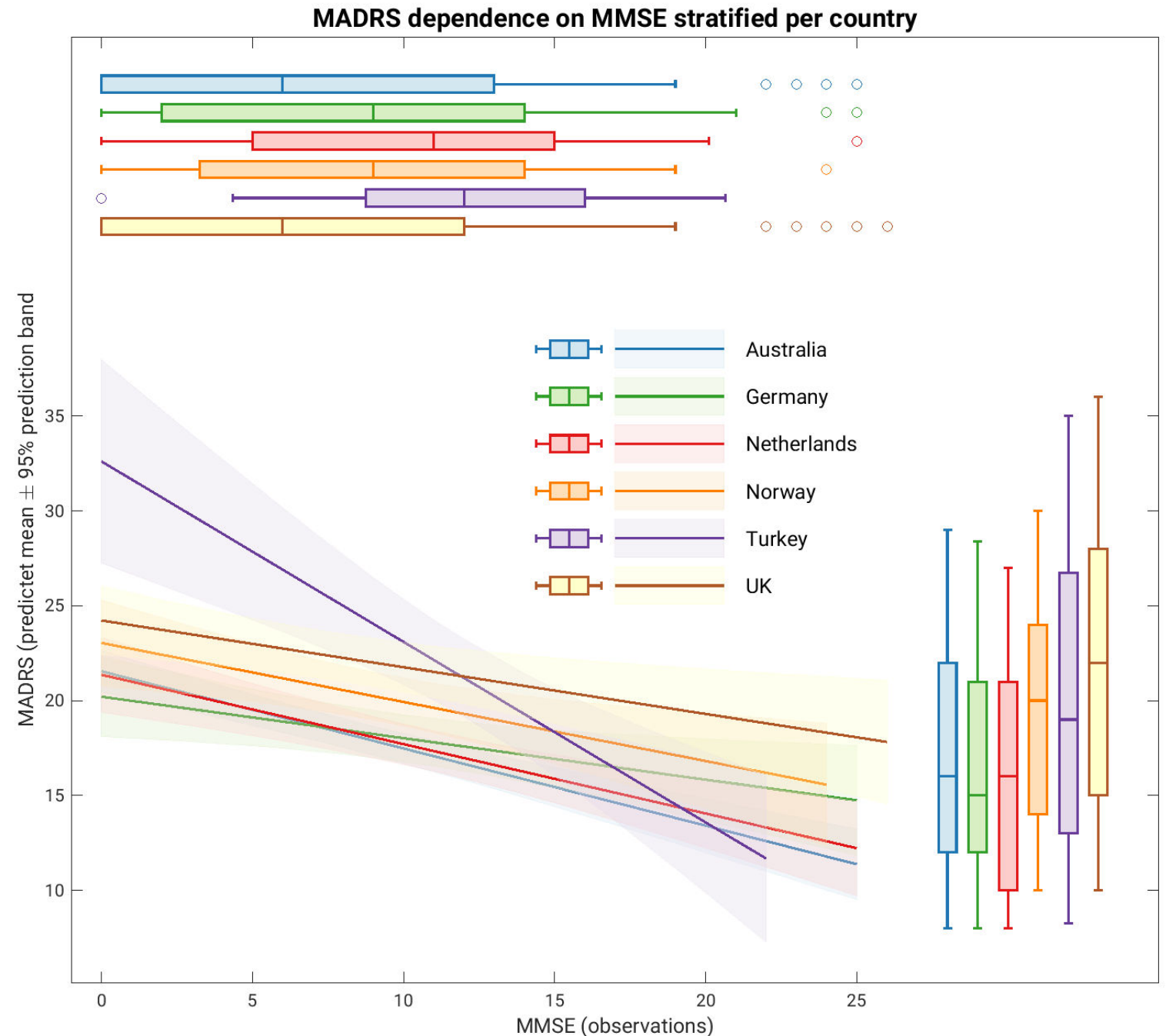
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Baseline data

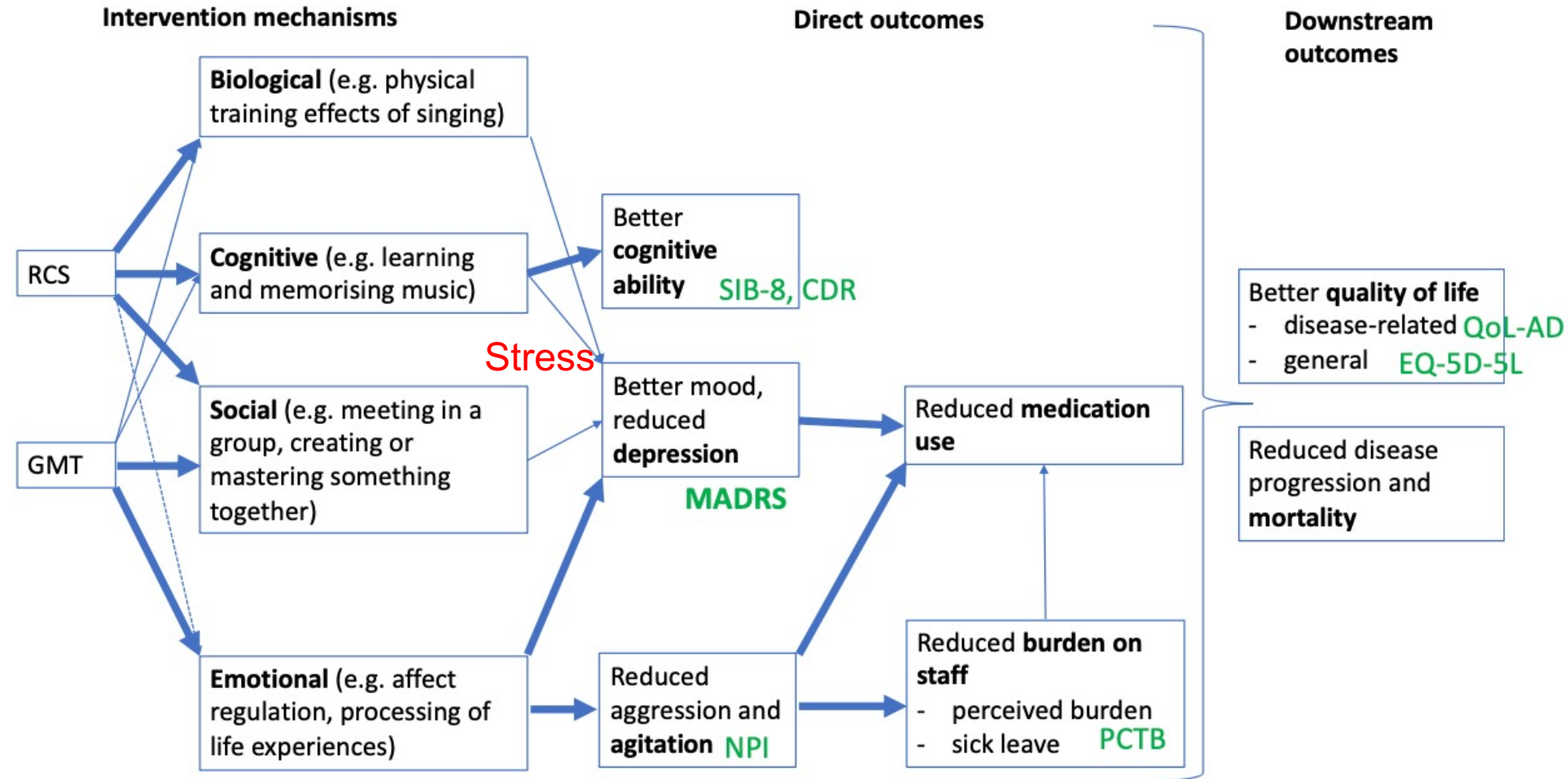
- Differences between countries in level of dementia and depression and their relationship
- May represent different health care systems

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in review





Towards personalised intervention



adapted from
Gold et al. 2019 *BMJ Open*

Figure 1. Proposed mechanisms and outcomes of music interventions in elderly care.
Abbreviations of outcome measures, see text.



Stress biomarkers: cortisol, alpha amylase

- GMT vs. RCS vs. "book reading"
- 183 residents
- Feasibility confirmed (with caveats)
- Stress decreased over time (pre-post session)
- No clear differences between conditions

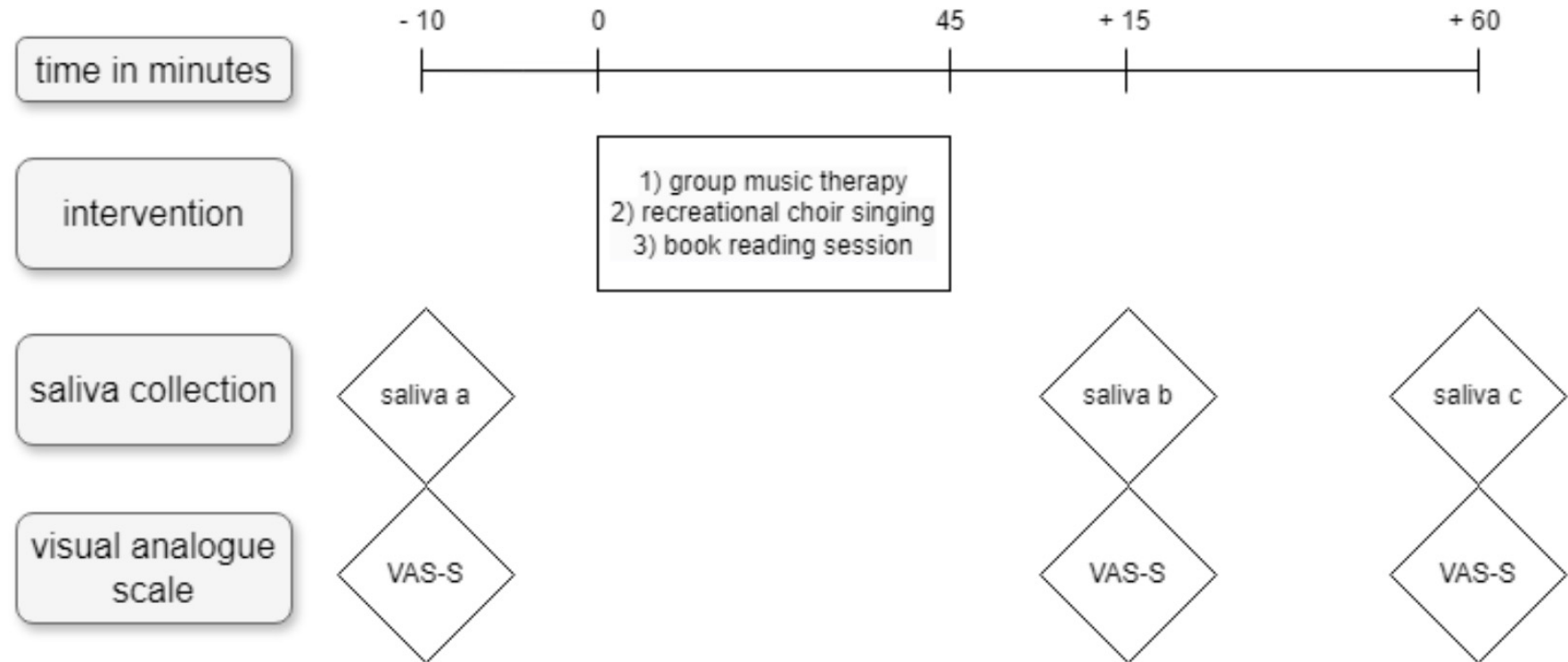
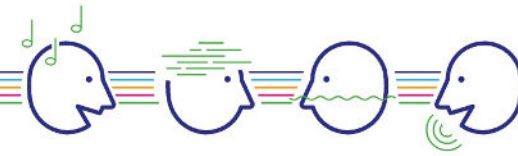


Figure 1b. Study procedure on one day of collecting saliva samples before and after the session. This procedure is repeated on three different days throughout the six-month intervention period.



Conclusion: Single-site versus multinational trials of psychosocial interventions

- Some of our *single-site trials*, all showing *positive effects of music interventions*:
 - Depression symptoms in nursing home residents (first cohort of MIDDEL; Baker 2022 *Lancet HL*)
 - Depression symptoms in nursing home residents (predecessor of MIDDEL; Werner 2015 *Aging Ment Health*)
 - Agitation in nursing home residents (individual MT; Ridder 2013 *Aging Ment Health*)
 - Depression in working-age adults (individual MT; Erkkilä 2011 *Br J Psychiatry*)
- Multinational trial(s): No clear effects of interventions across countries
 - Cultural (or genetic?) differences?
 - Variation in P-I-C-O difficult to control (Li 2020 *Ther Innov Regul Sci*)
 - Pragmatic vs. explanatory trials
 - Need more research linking mechanisms (biomarkers) with downstream clinical outcomes



<https://www.middel-project.eu/publications/>