Project title: Music Interventions for Dementia and Depression in ELderly care (MIDDEL): Measuring immediate changes in stress with salivary biomarkers
Project coordinator: Vigdis Sveinsdottir & Christian Gold
Consortium composition: NORCE Norwegian Research Centre, Bergen, Norway; University Medical Center Groningen, Netherlands; Carl von Ossietzky University Oldenburg, Germany
Poster presenter: Naomi Rasing

JPND research

MIDDEL
Music Interventions for Dementia and Depression in Elderly Care

Working hypothesis

Stress can have a negative impact on well-being and quality of life in care home residents with dementia. The effect of music as a potentially stress-reducing strategy was assessed in participants included in the multinational cluster-randomized controlled trial Music Interventions for Dementia and Depression in ELderly care (MIDDEL).

Aims & research questions

1) to detect **changes** in stress pre/post session (physiological and subjective);
2) to detect differences between **intervention groups** 1) group music therapy (GMT), 2) recreational choir singing (RCS), 3) a book-reading control condition;
3) to establish **feasibility** of saliva sample collection in care home residents with (advanced) dementia.
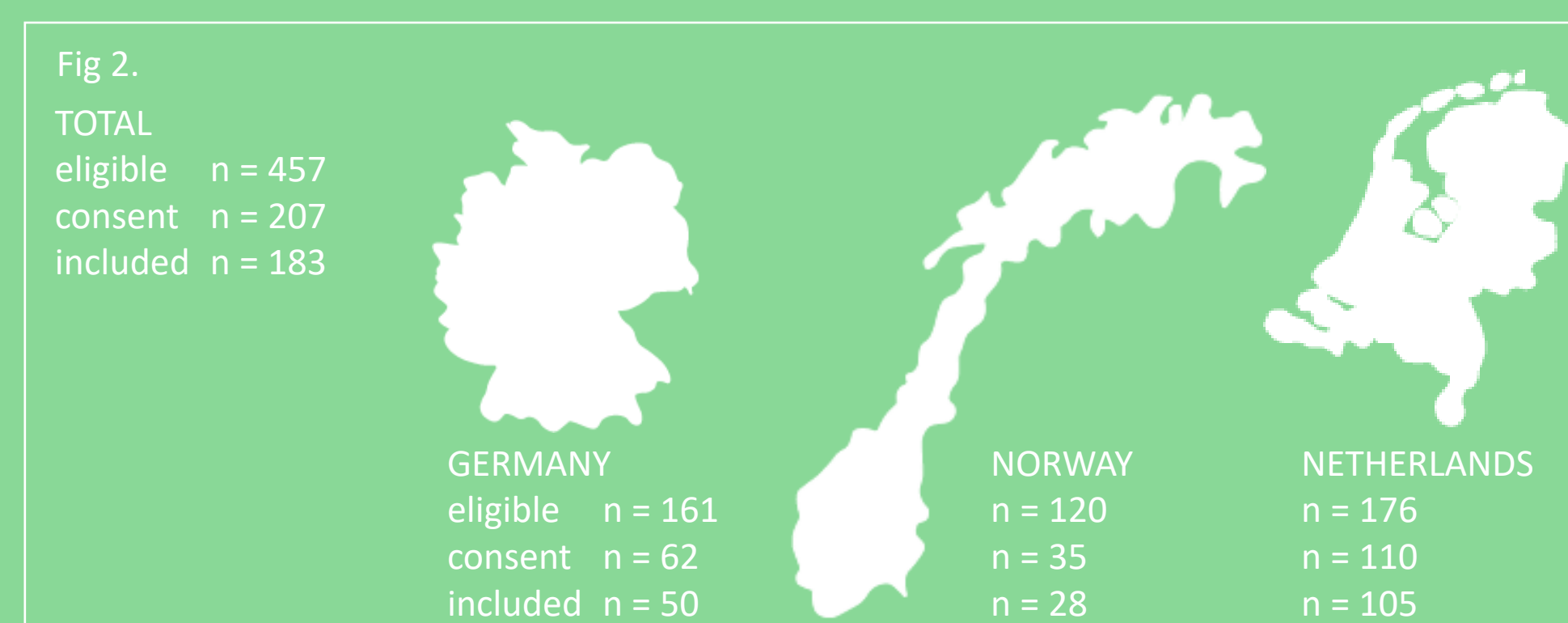
Workplan & Methods

- Clustered care home units and their residents were randomly allocated to one of three groups, with a six-month intervention period.
- Saliva was collected at three different timepoints (on a day a session took place approximately one, three, and six months after randomization) (fig. 1a).
- Saliva was collected before and after the session, along with a Visual Analogue Scale (VAS-S) indicating stress (from 0 – the least stress to 100 – the most stress you can imagine (fig. 1b).
- Pre/post session changes within groups were assessed using linear regression; differences between groups were assessed using multiple regression analyses, controlling for baseline values.

Figure 1a.

Figure 1b.
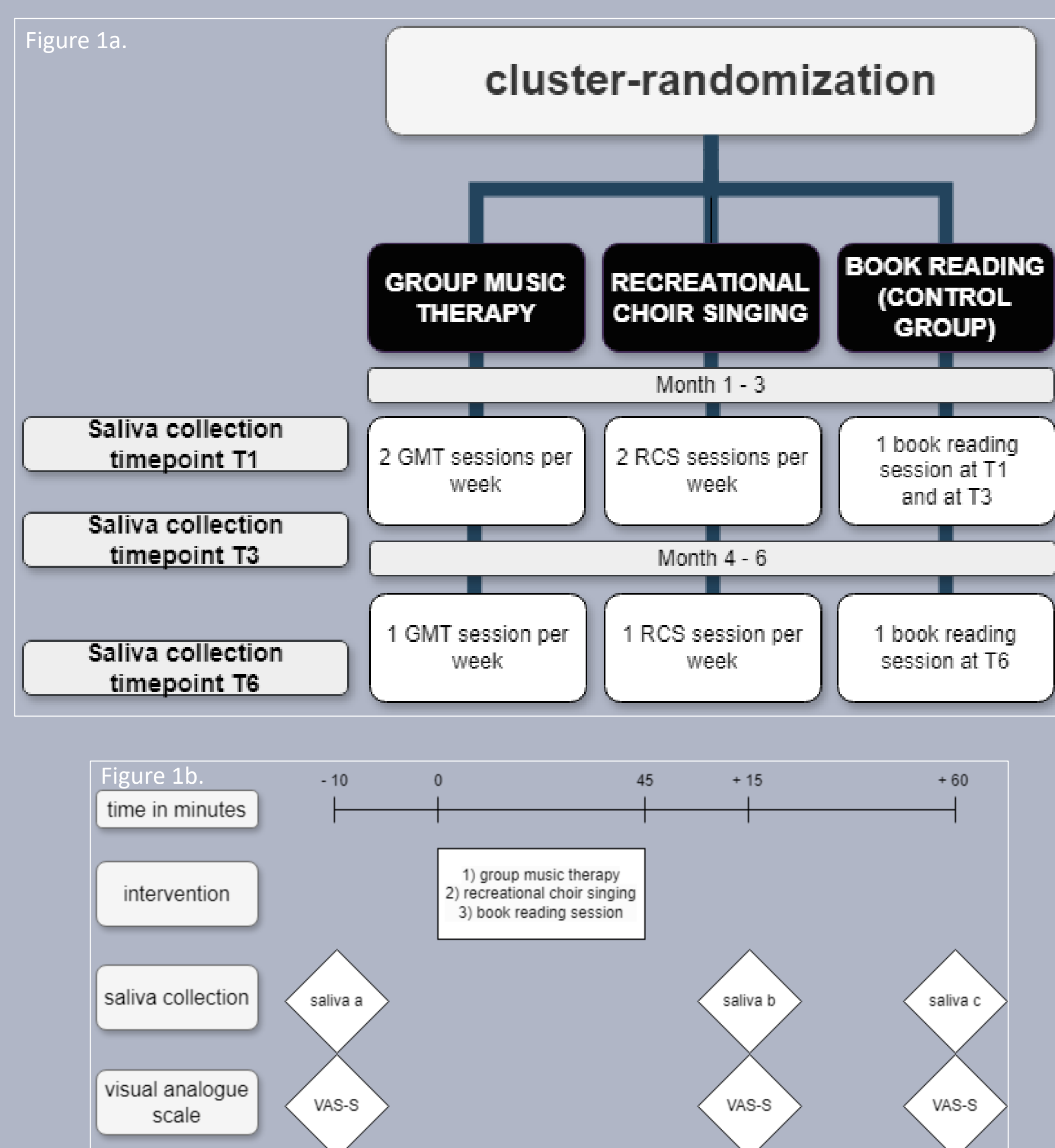
Participant characteristics

- **Informed consent** provided by 45% (n = 207) of eligible participants, 183 were included (fig. 2). Mean age was 84.5 years (SD = 7.1) and majority was female (n = 141, 77%).
- Most prevalent dementia diagnosis was **Alzheimer's disease** (37%), majority of participants had moderate to severe dementia and **mild depression**.
- Participants received GMT (n = 55), RCS (n = 72), or a book reading session (n = 56). Sessions started around 1 p.m. and attendance ranged from 49% to 95%.
- Saliva was also collected from non-attending participants.

Fig 2.
TOTAL
eligible   n = 457
consent   n = 207
included   n = 183

	GERMANY	NORWAY	NETHERLANDS
eligible	n = 161	n = 120	n = 176
consent	n = 62	n = 35	n = 110
included	n = 50	n = 28	n = 105

Milestones: *Saliva samples*

- Of 1014 saliva samples collected in 183 included participants. Of these, 671 (66%) were valid for alpha-amylase (sAA) assay, compared to 633 (62%) for cortisol (sCort) assay.
- A median of 7 out of 9 saliva samples was collected from participants, with a median of 9 collected samples in GMT compared to 6 in RCS and CONTROL.

Publication: *Study protocol*

Rasing NL, Janus SIM, Kreutz G, Sveinsdottir V, Gold C, Nater UM, Zuidema SU. The Impact of Music on Stress Biomarkers: Protocol of a Substudy of the Cluster-Randomized Controlled Trial Music Interventions for Dementia and Depression in ELderly Care (MIDDEL). Brain Sciences. 2022; 12(4):485. https://doi.org/10.3390/brainsci12040485

Key results

- Changes in subjective stress were significant for most timepoints/study arms, except for VAS-S pre-session to follow-up in GMT T3 and T6, RCS T6.
- Salivary alpha-amylase significantly changed at T1 in CONTROL (p=.032), at T3 in RCS (p=.032 and CONTROL (p=.028), at T6 in GMT (p=.009).
- Salivary cortisol significantly changes at T6 in GMT (p=.027) and CONTROL (p<.001).
- For sCort and sAA, no significant pre/post session differences between study arms.
- Subjective stress (VAS-S b) differed at T3 post-session between CONTROL and RCS (b=-9.350, t(105)=-2.39, p=.019) and at T6 between CONTROL and GMT (b=-6.021, t(99)=-2.19, p=.031.
- Most common confounders potentially affecting saliva compound were: drinking caffeinated beverages (86 – 93%), drinking juice (69 – 78%), and eating (59 – 67%) prior to saliva collection.

Significance & Impact

- Group interventions, including music therapy, are associated with a **reduction in stress** in care home residents with dementia.
- The large international cluster-randomized setting in which this study was collected, led to an impressively **large sample size**.
- Findings indicate it is **acceptable & feasible to collect** saliva in people with advanced dementia **non-invasively**.
- This study adds value to the body of knowledge on how biomarker research can be conducted in an effective and **meaningful way** in psychosocial research involving complex interventions for people with dementia.

Next steps & Future challenges

- More research is needed to differentiate between physical activation, arousal or stress. A moderation analysis and **sensitivity analysis** will be conducted including influence of possible **confounders** and non-attendance (passive control group) in the statistical model.
- In future studies saliva flow may have to be **stimulated** to increase chances of sufficient saliva fluid for assay.
- Physiological stress measured by sAA and sCort may differ from stress experienced by the person with dementia or observed by care staff. Therefore, the same person should fill out the VAS-S each time.

Stay informed about the MIDDEL trial & visit the trial website: https://www.middel-project.eu/

MIDDEL

Contact Naomi Rasing
0000-0002-9761-3705

NORCE
umcg
UNIVERSITY OF VIENNA
university of groningen
ArtEZ University of the Arts
CARL VON OSSIETZKY UNIVERSITÄT OLDENBURG