

MIDDEL Project Newsletter No. 2

Dear MIDDEL colleagues,

Here is a new informal update on the MIDDEL-project, the summer newsletter of 2021.

Many things have happened since I sent you the Christmas newsletter last year. We are generally in a better position with regard to the pandemic, with more and more care home residents and staff being vaccinated. We have also commenced recruitment and randomization in the European part of the trial—much delayed, but an important milestone nevertheless! Meanwhile, our Australian partners have finished the data collection for their 20 care home units (CHUs), and are now in the process of writing up those data for publication.



But while we may see more clearly now that much of the rain has gone, we can also see the obstacles in our way... There is a lot of activity and problem-solving going on across the European MIDDEL sites these days, and each of you have kindly provided a short update for this newsletter:

- **In Germany**, the team is busy organising all the licenses and translations for the questionnaires this spring, and have reached out to different nursing homes that are interested in participating in the project. In March, an information event was organised for all nursing home managers who wanted to know more about the study and requirements for participation. Contacts were established with several nursing homes who are willing to participate and are happy about this opportunity for their residents. According to the nursing home staff, baseline assessments and the start of group music therapy and choir singing will be possible in late summer/fall, depending on the rules concerning the pandemic. Until then, preparations are being finalised for the baseline assessments and additional staff are being hired: a study nurse, music therapists, and choir leaders.
- **In the Netherlands**, four care home organizations, with up to 8CHUs, will start with the MIDDEL-project this summer. As a first step, 3 out of 4 already sent out information letters to residents and their legal representatives. Six music therapists have participated in the online seminar/training. During the next weeks, baseline assessments will start in the first care homes. Luckily, researchers are allowed to visit the care homes for the assessments. The work on the questionnaires for the process evaluation of the MIDDEL-project has also continued. The purpose of the process evaluation is to evaluate process data on sampling quality (recruitment, reach) and intervention quality (relevance and feasibility, extent to which music interventions are performed). Stakeholders (care staff, informal caregivers, intervention providers, care home management) will be asked about the intervention quality using the questionnaires, which in turn will be used for understanding internal and external validity of effectiveness of the music interventions. Practical issues for the biomarker sub study are also being worked out, including the design of the REDCap database and where the biological samples can be stored in the correct way.
- **In Norway**, the team has been busy translating all forms and doing the necessary hiring and training to start up with the first CHUs earlier this spring. Four CHUs from Kinn municipality were included, and were randomized in April after completing baseline assessments (Fun fact: Our oldest participant was born in 1918!). The data has been entered into REDCap, music interventions are now ongoing, and the 3-month follow-up will start in July. In a new information meeting with care homes in a second municipality (the city of Bergen) this week, four CHUs agreed to start in the early autumn. According to plan, these will be followed by four more in the late winter. The process of preparing practical procedures and staffing for this second municipality is now ongoing, as are the ethics amendments necessary to implement the process evaluation and biomarker sub study in Norway.
- **In Turkey**, the project officially started on Feb 1, 2021. Three choir trainers and one psychologist were included in the project. Music therapist Yeşim Saltik, experienced with people with dementia, will come from

the Netherlands to work on the project. All elderly people in nursing homes in Turkey have been vaccinated, but so far no one in the project team has been vaccinated. For this reason, contact with nursing homes has not started yet. All ethical permissions have been completed, and necessary documents have been translated into Turkish.

- **In the United Kingdom**, new guidelines about visitors to residents of care homes were issued in May. While everyone has been vaccinated, there is still a high level of caution, since the past months have been traumatic for many care homes. The interpretation of the present rules is that a singing leader entering a home would currently need to work behind a transparent screen. Hand to hand contact is discouraged, which presents an obstacle to interactive music therapy. The next review of the rules will be around June 21st. The UK team is therefore recruiting homes over the coming 3 months, and visiting them from September, 2021 if allowed. A 2 ½ minute video is also being made to help with care home recruitment and will be shared with the research group. Meanwhile, we have to congratulate Harleen Rai, who is moving to Strathclyde University in Glasgow, Scotland to take up a 4-year post-doctoral fellowship. Linda O’Raw will be stepping in over the summer to recruit care homes, bringing her own experience of research in care homes and RCTs. Welcome, Linda!

DSMC meeting

On June 9th, the fourth meeting of the Data and Safety Monitoring Committee was held. The recruitment progress and an interim report of the current data was discussed, and the meeting minutes will soon be available in Dropbox (MIDDEL/Administration/Meetings). Norway has started collecting data on adverse events, but have not yet received any such reports. All remaining countries are advised to translate and distribute the adverse events form (found in Dropbox MIDDEL/Assessment/CRFs) which should be collected regularly from the respective CHUs throughout their participation in the study, and entered into REDCap. The DSMC will have their next meeting in October/November.

Informal get-togethers/coffee breaks

A few weeks ago, Naomi and Ulrike initiated an informal get-together/coffee break for those involved in the daily coordination of MIDDEL in the various countries. This was a great way for those working with the project on a day-to-day basis to discuss current issues and questions. If someone else among you would like to participate the next time we schedule such a get-together, please let one of us know and we will make sure to extend an invitation.

PI change

As we informed most of you during our meeting in Vienna last year, I am now taking over Christian Gold’s role as the PI of the international (and Norwegian) MIDDEL trial after having been the project coordinator for the past year. The change has been communicated to and accepted by the JPND and the Norwegian ethics committee, and will soon be visible on the [project webpage](#) as well. I am grateful for this new responsibility, and would also like to extend a big thanks to Christian for all of his work as the PI of MIDDEL. Luckily for us all, Christian will continue being part of the team as a researcher, and on a practical day-to-day basis things will in many ways continue as they have been up to now.

The next MIDDEL European partners meeting

It is soon time to schedule our next meeting for all the MIDDEL partners. The main topic to discuss here will be the recruitment: How will we handle the deviations from the original recruitment plan, also with regard to national funding, project periods and time to follow-up? Another important point on the agenda will concern the process evaluation. Although we wish that this meeting could happen in person, the Teams-format will still have to suffice for now. We will send out a “doodle” and a meeting invitation soon, and look forward to see you.

In the meantime, have a wonderful summer!

Best wishes,
Vigdis, on behalf of the Norwegian MIDDEL team



Music Interventions for
Dementia and Depression
in Elderly Care