Bergen, November 2014

Dear all,

We are now more than half way through the planned time period for the project. In this newsletter we have news about recruitment, past and upcoming events, and news from each site and the central study office as usual. The social component continued to be important (see the picture here from the meeting in Vienna in July this year). Many thanks to Łucja for her help in compiling this newsletter. I hope you will enjoy reading it and wish you all the best for the closing of 2014.

Best wishes

Łucja

1.) Recruitment to date

We have continued to focus primarily on recruitment. I can share the fantastic news that in November 2014, we crossed the number of 200 participants randomised! This is excellent, as it already makes TIME-A one of the biggest trials (if not the biggest) on a psychosocial
intervention for ASD. It is also a very clear testimony of the enthusiasm of the worldwide collaborative team that makes TIME-A so unique.

But is the glass half full or half empty? Probably both. Time is running. The original plan was to have 300 randomised by now. Every new participant will need a year to complete their participation in the study, not counting the time needed to analyse the data. We can try to squeeze that time a bit. Some sites (old and new) are doing very well, as indicated by steep curves in the diagram here, and may compensate for others that have been less successful in terms of numbers.

Brazil and the two UK sites have started recruiting. Austria, Korea, and Norway had to stop recruiting after less than 40 participants each. Other sites (Australia, Israel, Italy, USA) have continued to recruit further participants. Some sites have even asked if they are permitted to recruit more than originally planned. The clear answer: yes, please!

2.) Past events

In July, we had our annual in-person TIME-A meeting in Vienna. Among other topics, we also discussed effective strategies for recruitment and retention, specifically with a view to helping the ‘new’ sites to get started. The latest success of some of the late starters may indicate that this kind of collaborative tutoring has worked very well! Also otherwise, the meeting was a very nice experience, as the picture on the previous page indicates. After the meeting, many of us went to the World Congress of Music Therapy in Krems (near Vienna). A joint presentation focusing on clinical music therapy work and case vignettes was very well received. It even featured a newly composed TIME-A song (melody: “Do-Re-Mi”; lyrics: A. Oldfield/TIME-A team) that says a lot about collaborators’ experience of working on the project:
The TIME-A Song
Oh my dear, just starting up
Randomising what a trial
Gee, the child just won’t turn up
Far too busy for this trial
So we’ll have to test again
Late and running out of time
Team our problems are the same
And we keep coming back for more!

In addition to the in-person meeting and conference, we have kept the tradition of having online meetings in between. The last one in November was again focused on recruitment. Unfortunately, due to the time of day we only had participants from European countries. We are now trying to find a time for the next online meeting in January that considers the needs of American and Australasian sites in a better way.

3.) Upcoming events
Not only for the online meetings, also for the in-person meetings, it seems high time for us to move away from Europe. As we are in the study that never sleeps, what better place could there be than the city that never sleeps? (Or the state to which it belongs, anyway.) Our colleagues at Molloy College have been very successful in recruiting participants – 44 to date. We are curious to learn about the secrets of their success and would therefore like to suggest having the next meeting there. John Carpente and his team would be able to host the meeting in the last week of October 2015 (roughly 27th-30th, probably including a one-day conference). Please save the date and tell us what you think about this suggestion! Łucja will be in touch about practical arrangements.

4.) News from the central office
The biggest changes at GAMUT are that Karin Mössler is now on maternity leave (October 2014 to approx. August 2015) and that Monika Geretsegger has started in a 50% researcher position (November 2014 to October 2015). Heartfelt congratulations to Karin, and a warm welcome to Monika!
The responsibilities in the team are now as follows:

- General requests, including OC issues and randomisation requests, continue to go to Łucja. She will also continue to keep track of who is involved in the project (78 people and counting!).

- In the period from 10 December to 16 January, Łucja will be on holiday and Christian will be in charge of randomisation requests.

- Monika is responsible for UHEADS (registering new users, helping with technical issues). Her (new) email address is monika.geretsegger@uni.no.

- Marko Nouwens (marko.nouwens@uni.no) will continue to send out lists of which videos should be uploaded to UHEADS, as well as any necessary reminder emails for keeping deadlines. Please support him as well as possible! In some cases he might also get in contact with you if the data needed is not entered in OC. In general, please keep in mind that data entry should be done as soon as possible after an intervention has been completed. For the next video uploading round Marko will also ask you to upload 12 sessions instead of 10 since we experience frequently that videos cannot be used for microanalysis for different reasons (e.g. no sound, therapist and/or child are not visible, etc.).

5.) News from all sites

We have now reached the 5 month mark with our 4th cohort of participants from Australia. It was a smaller cohort of 8 children, and we continue to partner with an Autism specialist school who provided a venue for the music therapy sessions and the assessments. Joanne (Jo) Rimmer was the music therapist for these children, and she has facilitated some great sessions. One boy has extraordinary music skills and is a Beatles fanatic. Jo has worked hard to incorporate the songs he loves, such as "Come Together", improvisationally and will be hoping to present this work as a case study. Grace is progressing with the analysis of the improvised lyrics/dramatic role play of another participant from 2013, and will share more details as they unfold. We hope to start the next cohort in early 2015, so we have a little break now with the end of the year approaching bringing summer here in Australia.

Grace Thompson, University of Melbourne, Australia
It was wonderful to see the TIME-A team in Vienna this summer – thank you for visiting, and came back soon!

The TIME-A site here in Vienna is now about to close. As my fellowship from Aalborg University and employment with the University of Vienna ended on October 31, we needed to stop recruiting in spring this year. The 12-month follow-up assessment of the 16th and last participant is scheduled for January 2015. I would have liked to recruit a higher number of participants, but found this aspect of feasibility to be limited in the Viennese context. Other aspects such as retention and implementing assessment and intervention procedures turned out more successful. Together with Ulla, Łucja, and Christian, I have written up a full report on feasibility and acceptability of the TIME-A study design as reflected in the Austrian pilot cohort. The manuscript has just been submitted to a peer-reviewed journal.

Since November 1, 2014, my role within TIME-A has somewhat changed: I now hold a part-time researcher position at GAMUT which among other things includes further scientific and also some administrative work related to TIME-A. I look forward to spending one week each month in Bergen to work alongside the GAMUT colleagues directly in the central office.

Monika Geretsegger, Aalborg University/University of Vienna, Austria

We finally started with the first 4 participants in the Brazilian TIME-A. At this moment, we are applying the ADI-R in more 8 participants. The expectation is to randomize in 2015 more 15 participants. We will include another music therapist to work with us in 2015. In terms of publications, we expect to publish 3 or four articles related to Brazilian TIME-A project. We contacted during this year with many autism organizations and the Brazilian TIME-A study received a national scale as a consequence. We hope in the next year to contact many different publishers to get the publications of ADI-R, ADOS and SRS in Brazilian Portuguese (paying the copyrights to the WPS company).

Gustavo Gattino, Universidade Federal do Rio Grande do Sul, Brazil
After a very unstable summer in Israel we returned to work and began recruiting new children at the Jerusalem site. Looks like our new cohort will be about 6-7 children. These will be added to the 22 participants we already have. The music therapists and the two psychologists will continue with us and we have added Romi, a music therapist as a research assistant for a few hours a week.

We have some very exciting research projects that have come out of the TIME-A at the University of Haifa. Besides Tali's PhD on parent music therapy counseling, we have a master student who will soon deliver her thesis on vocal interactions of two sites (Israel and Austria). Another master student is looking at different elements of parent counseling interviews; two movement therapy students will be doing a quantitative study on embodiment by analyzing 25 videos from various countries. This will be co-supervised by a Laban expert, Dr. Nava Lotan who is a world renown on this topic. Lastly, we are continue to collect data on sensory profiles from all participants in Israel. This is with collaboration with the occupational therapy department at the University of Haifa.

Cochavit Elefant, University of Haifa, Israel

In Italy we had an intensive work as far as patients recruitment is regarded. Until the end of october 2014 we have enrolled 30 children to the TIME-A research programme; among these children, four dropped-out after being assigned to the control group condition. Seven children have just completed twelve months of music therapy/counseling sessions and had their outcome evaluation. Now four more children are waiting to be randomized.

The main problems regard parent difficulties to maintain same time and same day in the high intensity condition in therapy group.

Any way we are a little bit surprised in having so many parents who are interested in our project, and we begin to be excited expecting the resuts of the research.

On November 15, 2014 during the European Music Therapy day we will present the Time A (study protocol) in a conference in the Ferrara Conservatorio.

Filippo Muratori and Ferdinando Suvini, IRCCS Fondazione Stella Maris, Italy
Autumn in South Korea is very beautiful with clear blue skies, vibrant coloured trees and mountains with perfect weather with gentle breeze. Everybody who has been involved with Korean site TIME-A is working diligently towards the completing the first part of the TIME-A group. This involves two clinical psychologists with a research level of ADOS assessor, four music therapists, two music therapy professors with counselor degree, and one research assistant and myself.

So far 25 children enrolled, including 3 drop-outs. There were some real world research issue happening in Korea that two children missed out 12th month final assessments (one refused to have any more assessment without good enough reasoning, another moved to the U.S after the music therapy trial), and one child who was assigned to standard care, turned out to have received music therapy service outside of the TIME-A project. Apparently, this mother of the child valued music therapy so much that despite the facts that every one of us, professionals, explained the terms of research engagement clearly from the recruitment, intake interview, and regular counseling sessions, the mother still claimed that she didn’t know such terms. So these were little frustration on my part, but as we all know, we cannot control the people living in a real world. All other clinical works are up and running well.

From this year, I have a sophomore undergraduate music therapy student, Eajin Yoo, helping me with entering data into the OC system and UHEADS, and she is very reliable that I am happy with.

I am still planning to apply for the National Research Council in Korea next year for international collaboration fund, but as the funding from GAMUT is soon to be finished, I will close the first part of Korean site TIME-A with this existing 25 children. I have also re-applied for a year length research leave to my university, which I am currently waiting for the results from the executive board members’ decision. If everything is going well, I will be applying the NRF grants in Vienna, spring, 2015. Fingers crossed! Merry Christmas and Happy New Year to you All!

Jinah Kim, Jeonju University, Korea
With 9 participants randomised and recruitment stopped, the Norwegian site will likely remain as the smallest site in TIME-A. This is not completely unexpected. It has to do with the small size of Bergen as well as the organisation of care – eligible participants were quite hard to find. Karin’s maternity leave added another reason for having to stop recruitment now. In spite of its small size, the site has been important in adding a local dimension to the project. It has enabled us to make fruitful links to the university hospital, and it has also helped to develop the related “Shared moments” project that further investigates what happens in IMT sessions and how that might predict outcomes.

Christian Gold, Uni Research, Bergen

Greetings from the Rebecca Center for Music Therapy at Molloy College, USA! As usual, we had an eventful summer and fall that included another massive rainstorm, which flooded and destroyed our center. This resulted in delaying our randomizing process for cohort 4 as well as interfering with the 12-month testing process. Thanks to the hard work and diligence of Jesse Asch, Stephanie Cestaro, Laura DeGanarro, Michael Kelliher, Jill Lucente we are back on track with both randomization and treatment sessions. We have randomized 9 new participants and plan to have a total of 12 for this current cohort. We will begin randomizing our final cohort in February 2015. In regards to subprojects (collaboration with Molloy’s Speech & Language department and City of New York Graduate Center), we are inviting TIME-A participants to partake in an EEG study/measure investigating the relationship between auditory processing and music therapy outcomes. In addition, we have recently completed the data collection and analysis regarding our interrater reliability study of the IMCAP-ND’s Scale I: MEARS (very encouraging results!). Finally, Laura DeGenarrollo, ADOS assessor, and Dr. Laura Kestemberg (clinical supervisor) presented a paper discussing their preliminary data on the relationship between parent stress and social affect (comparing baseline data from TIME-A’s ADOS and SRS to PSI-4 and PDDBI) at the American Psychological Association (APA) annual conference. As we look to 2015, The Rebecca Center will be hosting a one-day conference, "Developmental Interventions for Autism:
Evidence-Based Research" on May 1st. Inspired by TIME-A, this conference, co-sponsored by the Interdisciplinary Council for Development & Learning (ICDL), will highlight developmental interventions and their place in the world of evidence-based research. The keynote speaker will be Dr. Devin Casenhiser and will feature a variety of presenters from an array of disciplines.

**John Carpente, Molloy College, Rockville Centre, NY, USA**

We are delighted to report that we have now randomised 7 children, and Laura started her music therapy work this week. We are currently working with three other schools and hoping to randomise another 12 as soon as possible. Our aim is to then randomise a further 20 (to make up a total of 40) by the end of February 2015. We are meeting and liaising with the other UK Time A sites, supporting each other and sharing resources. There are times when we feel things are a struggle or too slow - but mostly we are delighted to have this opportunity to create more music therapy work. We're all learning from the experience of being in this investigation.

**Amelia Oldfield, Anglia Ruskin University, Cambridge, UK**

From the UK London site we have received two reports:

The London arm of the UK study is now under way with seven children randomised so far. We are battling with the usual round of room negotiations but researchers and music therapists have been fantastic - flexible, responsive and courageous - not to mention the parents and children involved. East of England have just appointed their music therapist and will be up and running very soon too. This preliminary phase has highlighted the stark differences in provision of music therapy across the UK which is important for us politically too. Thanks to all the support from Norway and we look forward to the next phase.

**Anna Maratos, CNWL Foundation NHS Trust, London, UK**

Following an award by NIHR Health Technology Assessment to support recruitment to the trial in the NHS in England we have appointed two full time researchers to work on the study. Lavanya Thana, who has a background in psychology, will be working at sites in London and Sarah Faber, who has a background in music therapy, will be recruiting in the east of England.
The response of parents to plans for the study have been extremely positive with all those who are eligible agreeing to take part. We have an ambitious target of recruiting 100 children and their families over the coming months and the first 5 children have already been randomised since we started recruitment last month.

Mike Crawford, CNWL Foundation NHS Trust, London, UK

6.) Results: Popular science summary and list of publications

To conclude this newsletter, we would like to share with you the current popular science summary as well as the impressive list of publications related to the project from the annual report to the Research Council.

Current popular science summary of TIME-A (October 2014)

This project aims at investigating the effects of improvisational music therapy in children with autism spectrum disorder. Now in its second year, it has received scientific support from a newly published update of a Cochrane review on autism. In this review that summarises the worldwide evidence to date, researchers involved in the TIME-A project (Geretsegger, Elefant, Mössler and Gold) found that music therapy improves social communication and interaction skills (core features of autism), as well as social adaption skills and the quality of relationships with parents. However, the ten studies included in this review only examined short- and medium-term effects and show methodological limitations. Therefore, the review supports the TIME-A project both by stating that music therapy can be effective, and that there is still a need for research. Specifically, long-term effects and the relational qualities of music therapy have not received enough attention but are of central interest in TIME-A. How to work effectively in music therapy is also of importance. International consensus guidelines for improvisational music therapy as a child-centered and relational approach have been developed (Geretsegger, Holck, Carpente, Elefant, Kim and Gold, submitted). These guidelines will help music therapists to work consistently across countries. They emphasise the child’s individual process by giving therapists a guiding focus but without restricting them too much. This is crucial when working
with relational qualities of musical interactions that need to be child-, process-, and context related. Focusing on the mechanisms of change (what makes the therapy effective), TIME-A researchers have developed several assessment tools to look at developmental steps in autism on a musical and relational level. After successful reliability tests, they are now ready for use in projects related to TIME-A. Finally, the study has also expanded to new countries (England and Italy).

Current publications related to TIME-A (October 2013-September 2014)

2014:


2013:


