1. LAUSUNTOPYYNTÖ

Tampereen yliopisto, Ihmistieteiden eettinen toimikunta

TUTKIMUS: MEASURING INFANT NEUROCOGNITIVE DEVELOPMENT: EEG AND EYE-TRACKING IN SOUTH AFRICA

TUTKIMUKSESTA VASTAAVA HENKILÖ: Jukka Leppänen, Tutkimusjohtaja, Infant Cognition group, Lasten terveyden tutkimuskeskus, Lääketieteen yksikkö, B-rakennus, Medisiinarinkatu 3, S-posti jukka.leppanen@uta.fi, puh. 045 229 6938

PERUSTELU LAUSUNTOPYYNNÖLLE: Tutkimuksen osallistujina ovat alaikäiset lapset. Tutkimuksen rahoittajat edellyttävät lausuntoa. Tutkimuksessa ei puututa osallistujien fyysiseen koskemattomuuteen.

Tutkimus tehdään Mopanissa, Etelä-Afrikassa, osana Bill ja Melinda Gates-säätiön Grand Challenges South Africa –tutkimusohjelmaa. Vaikka tutkimuksen ensisijainen eettinen ennakkoarviointi on tehty Etelä-Afrikassa (Witwatersrandin yliopistossa), pyydän lausuntoa myös Tampereen ihmistieteiden toimikunnalta, koska i) osallistun tutkimukseen Tampereen yliopiston työntekijänä ja ii) osa tutkimuksessa kerättävästä aineistosta (lasten silmänliikerekisteröinnit) lähetetään analysoitavaksi ja säilytettäväksi Tampereen yliopistoon. Aineisto vastaanotetaan ja talletetaan koodatussa muodossa.

Tutkimukselle on saatu puoltava lausunto Witwatersrandin yliopiston eettiseltä toimikunnalta (päätös tämän hakemuksen liitteenä).

SALASSAPIDETTÄVYYS: Hakemuksen salassapidettävyydelle ei ole perusteita.

Tampereella 5.5.2018 Jukka Leppänen

3. TUTKIMUSSUUNNITELMAN SUOMENKIELINEN TIIVISTELMÄ

Tutkimusryhmä: Denise Evans, Health Economics and Epidemiology Research Office, University of Witwatersrand, Etelä-Afrikka; Peter Rockers, Department of Global Health, Boston University, USA; Amanda Tarullo, Department of Psychological and Brain Sciences, Boston University, USA; Jukka Leppänen, Child Health Research Center, University of Tampere; Günther Fink, Chan School of Public Health, Harvard University, USA; William Fifer, Columbia University, USA; Charles Nelson, Harvard University, USA

Tutkimuksessa selvitetään lasten neurokognitiivista varhaiskehitystä 6, 15 ja 24 kk iässä. Tutkimukseen osallistuu 540 lasta Limpoposta, Mopanin piirikunnasta Etelä-Afrikasta. Neurokognitiivista varhaiskehitystä arvioidaan aivojen sähköisen toiminnan (EEG) ja silmänliikkeiden rekisteröintiin perustuvilla menetelmillä. Puolet tutkimuksen osallistujista tulee perheistä, joille on tehty lapsen varhaiskehitystä tukeva interventio (lapsen vanhemmille on välitetty lapsen kehityksen tukemiseen ja hyviin ravintotottumuksiin liittyvää materiaalia sosiaalityöntekijöiden kautta). Tutkimuksessa vertaillaan neurokognitiivisen kehityksen profiileja interventio- ja kontrolliryhmien välillä, sekä suhteessa muihin lapsen kehityksen ennustekijöihin (ravinto, psykososiaalinen kasvuympäristö).

Tampereen yliopisto osallistuu tutkimuksen silmänliikemittauksiin. Silmänliikkeiden rekisteröinti on yksi imeväisikäisten lasten kognitiivisten ja sosiaalisten taitojen tutkimuksessa käytettävistä menetelmistä. Tutkimusaineiston keruu toteutetaan kokonaisuudessa Mopanissa, Etelä-Afrikassa. Tutkimusaineisto kerätään tutkittavan vanhemman tai huoltajan suostumuksella käyttäen tutkimussuunnitelmassa kuvattuja menetelmiä. Lasten silmänliikerekisteröinnit lähetetään analysoitavaksi ja säilytettäväksi Tampereen yliopistoon. Aineisto vastaanotetaan ja talletetaan koodatussa muodossa. Tutkimuksen ensisijainen eettinen ennakkoarviointi tehdään Witwatersranding yliopiston eettisessä toimikunnassa.

4. ETHICAL CONSIDERATIONS ANNEX FOR PROPOSAL: MEASURING INFANT NEUROCOGNITIVE DEVELOPMENT: EEG AND EYE-TRACKING IN SOUTH AFRICA

PI: Jukka Leppänen, Infant Cognition Laboratory, Center for Child Health Research, School of Medicine, University of Tampere, FIN-33014, Finland

4.1 Background and Justification

The research participants in the proposed study include human infants. The inclusion of infant participants, who are not able to give informed consent themselves, is essential for achieving the proposed research aims and for enhancing our knowledge of the key determinants of human neurocognitive development and well-being. In the following sections, I address the ethical issues that are raised by the proposed research, particularly issues raised by the involvement of infants and non-invasive recording of behavior.

4.2 Validity of Research Methods and Statistical Power

Research methodology. The research methodology is based on tried and tested EEG and eye-tracking paradigms that have been developed in the context of our own and others' researchers' previous studies. The proposed methods are non-invasive and well-suited to be used in research with human infants.

Statistical Power. As described in the proposal, the study is powered to detect a medium effect size ($f = 0.25$) at an alpha level of 0.05. A medium effect size is anticipated based on prior literature.

4.3 Ethical approvals

For all research, approval will be sought from the Ethics Committee of the primary research site. Each participating laboratory applies for ethical permission from the respective institutions for the relevant parts of the study.

4.4 Recruitment and Consent

Participants will be recruited from an ongoing intervention study in Greater Tzaneen and Greater Giyani, Mopani, South Africa. *Consent*: Before the study is commenced, an informed, written consent will be obtained from the child's parent/legal representative. The consent will be obtained by an individual designated by the PIs who is adequately trained, knowledgeable about the study, and capable of obtaining consent appropriately. The parent will be given adequate time to consider information provided and the risks and benefits to the child. Researchers will ensure that the parent understands the elements of the informed consent process by asking parents if they have questions about any of the procedures before asking them to sign the consent form. Participating in the study does not involve financial inducements.

4.5 Testing Procedures and Evaluation of Burden, Risks, and Benefits

The parent(s) or the legal representative will be with the child at all times during testing sessions and will be able to withdraw consent at any time during the study.

Burden: Infants participate in one testing session per visit that includes:

i) A 15-minute EEG recording
ii) A 15-minute eye-tracking while the infant is viewing visual stimuli on computer screen.

In all testing sessions, the protocols will be monitored to ensure that the level of burden is appropriate for infants at the proposed age and short breaks will be kept during picture viewing to ensure comfort for participants. For infants and children who do not find the testing protocol comfortable, testing and training will be stopped. The parent(s) or the legal representative will be with the child at all times during testing sessions and will be able to withdraw consent if they consider it in the child's best interests.

***Risks**:* All the techniques conform to the health and safety requirements set out in European Directives. There are minimal risks posed by the proposed procedures. Short breaks will be kept during the testing sessions to ensure comfort for participants. If the infant finds the testing procedure uncomfortable, testing will be stopped. The procedures will be monitored to ensure that it is appropriate for infants in the proposed populations.

Benefits. There are no direct benefits from participating in the proposed studies. The result from the study is expected to lead to increased knowledge of brain and behavioral development during infancy. In future, the methodology developed in the present study could potentially be applied in diagnosis of atypical development in early infancy.

4.5 Data Protection (confidentiality)

All research data, including questionnaire responses and eye-tracking data will be given a coded identification number and stored on USB memories and computers. The data will be transferred via secure internet connection between South Africa and Finland. Coded data will be kept for the amount of time specified by funding agency regulations (typically 15 years) and then destroyed using appropriate methods. The data will be released in "coded" format to researchers outside the primary laboratories and only in the extent that is necessary for the purposed collaborative analyses.

4.6 Insurance Coverage

NA

4.7 Results and Management of Incidental Findings

As a general rule, information about individual participant's eye-tracking data will not be made available to participants (although participants will have the right of access to data concerning him or her). The data collected in the proposed studies are most meaningful when analyzed on a group level and the results are primarily of theoretical interest. The results will be reported in scientific conferences and journals. Given the nature of the data and remote data collection, it is unlikely that the researchers at the university of Tampere will deal with incidental findings in the study. If the researcher sees something abnormal at any time during the research sessions s/he will notify the parent/legal representative and encourage them to seek care by their primary care physician. If the researcher has reasonable cause to believe that previously unreported abuse is occurring, s/he will together with the local study team in South Africa comply with the national law by filing a child abuse report to child protection authorities and will inform the parent/legal representative about the intended disclosure and the reasons for the disclosure.

UNIVERSITY OF TAMPERE
ETHICS COMMITTEE FOR HUMANITIES OF THE TAMPERE REGION

Statement 34/2018 on the request for statement 22/2018: "Measuring infant neurocognitive development: EEG and eye-tracking in south Africa" (tutkimusjohtaja Jukka Leppänen)"

The committee's statement: The committee gives a positive statement. The research does not entail ethical issues. It can be carried out according to the research plan.

Tampere, May 21st, 2018

	p.p.
Chairman	Kirsti Uusi-Rasi
Secretary	Heikki Eilo