EVOTION
BIG DATA SUPPORTING PUBLIC HEARING HEALTH POLICIES

Work Package 7
Validation of the EVOTION platform

Professor Doris-Eva Bamiou

2nd Advisory Board meeting
Milano, 26 September 2018

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 727521

WP7 objective

- To carry out the clinical and technical evaluation of the EVOTION platform as well as its evaluation as a public health policy-making tool for HL
- Within WP7 the delivery of the clinical study is critical as it feeds big data into the EVOTION data repository to enable the validation of the platform

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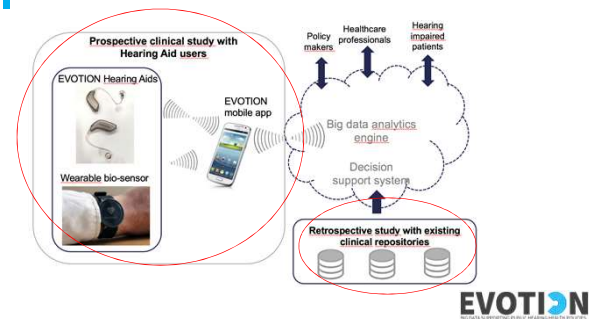
WP7 within the project



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WP7 achievements

- Unified clinical protocol & study pathway
- Ethics applications and approvals
- Finalization and development of test & auditory training material
- Identification and purchase of equipment
- Clinical validation underway, recruitment to be completed in October
- Extraction of retrospective data exceeded initial targets
- 990 patients recruited so far

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Summary of Work per Task

Task	Completed work or Action plan
T7.1 Evaluation Design and Ethics Approval (leader: UCL, M1-M24)	Unified clinical protocol, ethics approvals, amendments and ongoing ethical monitoring, D7.1 submitted in Jan 2017, Ethics Board (EB) with Clinical, GDPR and Data Management subgroups, 1st EB meeting (18/05/2018)
T7.2 HA user Data Collection (leader: UOA, M6-M17)	Ongoing recruitment, to be completed in October and recording of patient data in the EDR, D7.2 submitted April with 208 patients recruited, D7.2 Part 2 with full non real-time dataset (inc. audiological, cognitive, personal, occupational) due M30
T7.3 Technical Evaluation (leader: ICCS, M27-30)	M27-30: testing of performance, scalability, usability, privacy, security and accuracy of the Big Data Analytics-enabled decision making platform using a Technical Evaluation Framework
T7.4 Validation of EVOTION platform as a public health policymaking tool (leader: IPH, M27-32)	M27-M32: Big Data Analytics and decision support system will be checked against policy-making requirements using questionnaires and qualitative analysis on small focus groups of stakeholders
T7.5 Clinical Evaluation (Leader: GST, M27-33)	M27-M33: Correlations will be explored between HA usage & satisfaction and (combinations of) factors such as medical history, level of independence, socioeconomic factors etc.

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Deliverables

- D7.1 'Study protocol and Ethics Approval Application Report': detailed description of the clinical protocol. Submitted in Jan '17.
- D7.2 'Collection of non-real time hearing aid under data version 1': cumulative data including Pure Tone Audiogram, epidemiological and medical history data (e.g. family history of hearing loss, medication history, duration and cause of HL, education level). Submitted in May '18.

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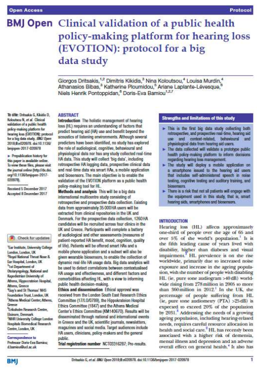
Clinical protocol

- Unified with all 4 clinical partners
- Published in Open Access journal


Open Access
Protocol
BMJ Open
Clinical validation of a public health policy-making platform for hearing loss (EVOTION): protocol for a big data study
Giorgos Dritsakis, Dimitris Kikidis, Nina Koloutsou, Louisa Murdin, Athanasios Bibas, Katherine Ploumidou, Ariane Laplante-Lévesque, Niels Henrik Pontoppidan, Doris-Eva Bamiou

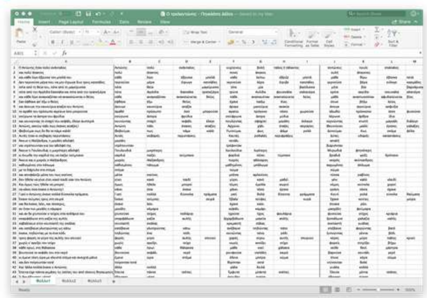
Ethics approvals

- UK ethics approval for UCL & Guys & St Thomas's (REC ref: 17/LO/0789, 9/6/2017) and minor amendment approval (13/11/2017)
- Athens Medical Centre ethics approval (protocol number KM140670, 3/4/2017)
- University of Athens ethics approval (protocol number 1714004926, 12/10/2017)
- UK local approvals at Guys & St Thomas's NHS Foundation Trust, Royal National Throat Nose and Ear Hospital (UCL Hospitals NHS Trust) and James Paget University Hospital (UCL's external collaborator)

Test & Auditory Training material

- Greek translation of HUI and GHABP questionnaires (not available previously)
- Development of the (Greek & English) material, design and rules for the auditory training component of the mobile app
- Provision of existing English material and rules, and development of new Greek material for a 'Words in Noise' mobile test
- Development of (English & Greek) material and rules for a digit recall mobile test
- Material and rules for a self-administered pure tone audiometry mobile test
- Feedback on interface design in order to be user-friendly
- Development of instructions and guides for use of hearing aids and mobile tests
- Feedback for verification and bugs
- Part of this was WP5 work but was relevant to WP7

Auditory Training in Greek



Crazy Antonis (Τρελαντώνης, Π. Δέλτα)
For Whom the Bell Tolls (E. Hemingway)
The Scent (Patrick Zueskind)

Auditory Training - example

Snowball

label	wave	end	sentence	kw1	kw2	kw3	kw4	blank	fw1	fw2	fw3	fw4	blank	dfw1
SB0001	SB0001	1	"I need to go down there Watson."	need	go	down	there		read	know	round	where		near
SB0002	SB0002	0	"I simply must" said Sherlock Holmes	simply	must				singly	just				quickly
SB0003	SB0003	0	at the breakfast table	breakfast	table				breathless	stable				steadfast
SB0004	SB0004	1	on Thursday morning.	Thursday	morning				firstly	warning				thirsty
SB0005	SB0005	1	"Go where?" I asked.	go	where	asked			know	there	passed			so
SB0006	SB0006	0	"To Dartmoor"	Dartmoor					Dartford					
SB0007	SB0007	1	"To Kingsbury."	Kingsbury					Finsbury					
SB0008	SB0008	1	"Yes of course" I said.	Yes	course	said			guessed	horse	sighed			yet
SB0009	SB0009	0	"Well everybody in the country"	well	everybody	country			hell	anybody	county			tell
SB0010	SB0010	0	"is talking about"	talking	about				walking	without				taking
SB0011	SB0011	1	"the case down there."	case	down				place	round				race
SB0012	SB0012	0	I always know	always	know				almost	go				away
SB0013	SB0013	1	when Holmes is interested in a case.	when	interested	case			one	interrupted	chase			men
SB0014	SB0014	0	He reads all the newspapers	reads	all	newspapers			needs	calls	neighbours			feeds
SB0015	SB0015	0	he walks up and down the room	walks	down	room			looks	round	gloom			talks
SB0016	SB0016	1	and doesn't speak for hours.	doesn't	speak	hours			mustn't	squeak	showers			wasn't
SB0017	SB0017	1	He did all those things yesterday.	did	those	things	yesterday		had	knows	thinks	everyday		hid
SB0018	SB0018	0	He didn't answer	didn't	answer				hadn't	after				isn't
SB0019	SB0019	1	any of my questions.	any	my	questions			many	mine	sessions			plenty
SB0020	SB0020	0	But I knew it was because	knew	because				drew	course				do
SB0021	SB0021	1	of the mystery at Kingsbury.	mystery	Kingsbury				history	instantly				misery
SB0022	SB0022	1	The morning papers were on the table.	morning	papers	table			warning	painters	stable			evening
SB0023	SB0023	1	They were full of questions.	full	questions				call	mentions				filled
SB0024	SB0024	1	What's happening at Kingsbury?	what's	happening				lots	happily				once
SB0025	SB0025	1	Where is Snowball?	where	Snowball				there	noble				care
SB0026	SB0026	1	Who killed John Straker?	killed	John	Straker			called	Don	Baker			grilled
SB0027	SB0027	1	What are the police doing?	what	police	doing			want	please	ruined			watch
SB0028	SB0028	0	Can they find the horse	can	find	horse			man	mind	house			ran
SB0029	SB0029	1	before the big race next week?	before	race	next	week		because	case	wrecked	leak		beyond
SB0030	SB0030	0	Snowball was a well known racehorse	Snowball	known	racehorse			Snowden	shown	course			trouble

The 'Snowball' story implemented in the EVOTION AT mobile app:

- The story is divided into phrases.
- Each phrase has 1-4 keywords (kw1-kw4) and for each keyword there are 1 or more foils (fw or dfw).

Identification of equipment

- Continuous collaboration of clinical partners with their procurement departments to find mobile phones and sensors that (a) fulfilled the technical requirements, (b) were available in both UK + Greece and (c) were within the allocated budgets
- Purchase of 1180 Samsung A3 (2017) mobile phones by all 4 clinical partners in Greece and UK
- Choice of the Huawei Fit wearable bio-sensor and ongoing communication with Huawei exploring resolution of technical issues
- Consortium strategic decision to recruit patients equal to the number of phones that could be procured and offer a phone to all patients to maximise number of data points

Prospective clinical study design

- 6 clinics in the UK, Greece and Denmark (including OTC and James Paget University Hospital as additional sites)
- 1220 adults with mild to severe HL referred for a HA
  - No dementia, willing to use HAs for 2 hours/day, able to use a smartphone
- Battery of audiological and other assessments
- Smart HAs based on commercially available Oticon Opn™
- Smartphones and bio-sensors for collection of HA usage data in different contexts
- Mobile application including:
  - A self-administered speech-in-noise test
  - An auditory training programme
  - A digit recall test
  - A self-administered pure tone audiometry test
  - Ratings of HA benefit and self-reporting of noise exposure

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Management of unforeseen events

Issue / challenge	Management / mitigation
Budgeting constraints & procurement issues => 1180 phones could be purchased in UK and Greece, technical issue with bio-sensor	• Decision to recruit patients who will all get a phone, only a subset will get a sensor to maximize number of data-points
Incompatibility of hearing aid fitting software with UCL Auditbase patient system	• Inclusion of JPUH as external collaborator
Dependencies of clinical study on technical work (e.g. IT upgrades, Auditdata work) and relevant approvals > study start delay	• Expedited patient recruitment • Inclusion of OTC as additional clinical site
Missing data	• Data will be entered in follow-up visits • Participants are asked if they are having technical issues and if they still want to be part of the study
Ongoing issues with mobile application & difficulty of participants to download updates	• Updates with improvements • Help from clinicians

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Clinical study flow

Abbreviations

MoCA: Montreal Cognitive Assessment,

PTA: Pure Tone Audiometry,

HADS: Hospital Anxiety and Depression Scale

GHABP: Glasgow Hearing Aid Benefit Profile

HUI3: Health Utility Index Mark 3

HA: Hearing Aid,

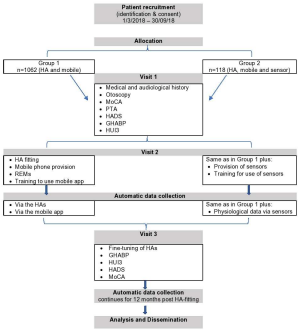
REM: Real Ear Measurement

Time per visit

Visit 1: 90 minutes

Visit 2: 120 minutes

Visit 3: 45 minutes



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Visit 1: Cognitive screen and Questionnaires

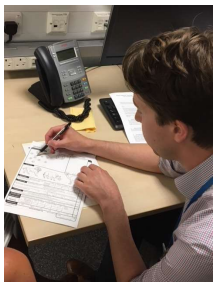

Photo taken at Guy's and St. Thomas' hospital

Photo taken at University of Athens 'Ippokrateion' hospital upon patient consent.

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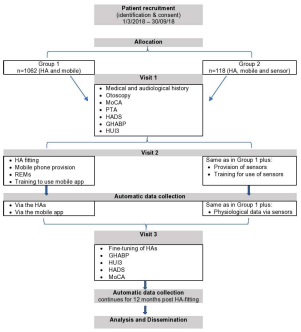

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Visit 2: EVOTION Hearing-Aid fitting

Photos taken at University of Athens 'Ippokrateion' hospital

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Visit 2: Real-ear measurements

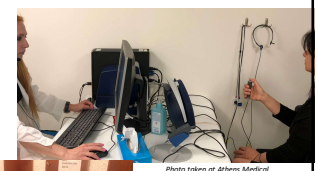


Photo taken at Athens Medical Centre

Photo taken at Guy's and St Thomas' hospital

Photo taken at University of Athens 'Ippokrateion' hospital

Visit 2: Mobile phone administration

Photo taken at Guy's and St. Thomas' hospital

Clinical study flow

Abbreviations

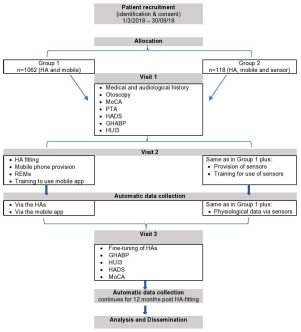
MoCA: Montreal Cognitive Assessment,
PTA: Pure Tone Audiometry,
HADS: Hospital Anxiety and Depression Scale
GHABP: Glasgow Hearing Aid Benefit Profile
HUI3: Health Utility Index Mark 3
HA: Hearing Aid,
REM: Real Ear Measurement

Time per visit

Visit 1: 90 minutes

Visit 2: 120 minutes

Visit 3: 45 minutes



Visit 3: Entering data in the EVOTION dashboard

Photo taken at Guy's and St. Thomas' hospital

Supporting activities: Recruitment promotion

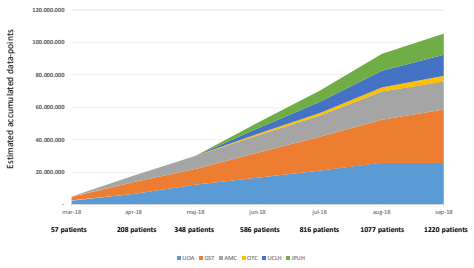
Recruitment

- A total of 990 patients have been recruited so far.
- Approximately 90% of target population.
- Expedited patient recruitment to be completed by October 2018:

Site	M15-M18 (April)	M19 (May)	M23 (Sept.)	M24 (Oct.)
GST	86	112	355	380
UOA	77	144	290	300
AMC	45	92	175	200
UCL	-	-	145	200
OTC	-	-	25	40
Total	208	348	990	1120

Recruited patients & estimated amount of data

Estimated number of accumulated data-points that will be collected in 12 months for real-time HA data for the total number of patients recruited per month from all clinical sites



Assumptions:
- 12 months of data/patient
- 2 hours/day
- 2 HAs
- 60 data-points per HA/hour

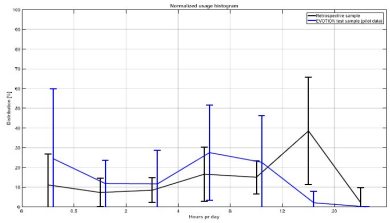
Retrospective data

OTC
- Audiograms from 45,451 adults from OTC's existing clinical repository uploaded on the Evotion Data Repository (EDR)
- Distribution can be basis for comparison with the EVOTION study findings
- US data on prevalence of hearing loss can be used as reference for monitoring of noise induced hearing loss and modelling of Permanent Threshold Shifts in WP3

GST
- 10425 patients extracted
- Audiograms, gender, age uploaded into EDR

➢ **Retrospective data will be analyzed together with and based on the prospective data results**

Example: HA usage



Normalized usage histogram showing the mean and standardized deviation for a retrospective sample and an EVOTION pilot sample. The normalization is applied to the individual HA data, and thus this characteristic does not take into account if the hearing aid was used for say a month or a year.

Pilot Study

- Conducted M13 - M14
- 10 patients
- Time needed per patient recorded
- Refinement of procedures (informative session, mobile phones)
- Finalization of flowchart

Results: Preliminary prospective data I

Demographic data from ¾ clinics (UOA, GST, AMC) M15 - M18 (April '18)

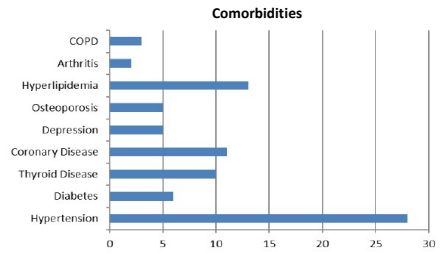
Demographic data	
Age	Mean: 60.97 years old
Gender distribution	Male: 50.96%, female: 49.04%
Education	51% mainstream education
Independence level	72% independent, 6% living with family
Employment	27% regular or part-time
Motivation for HA	47% self-motivated, 24% family/friends

Results: Preliminary prospective data II

Medical history data from ¾ clinics (UOA, GST, AMC) M15 - M18 (April '18)

Otological and medical history data	
Dexterity	86% adequate for both left + right
Otoscopy problem	22% yes (e.g. wax)
Ear discharge	6% yes
Ear surgery	Right ear 8% yes Left ear: 5% yes
Audiological findings	49% severe HL, 41% mild/moderate HL
Asymmetry in hearing loss	26% yes
Fluctuation of hearing	15% yes

Results: Preliminary prospective data III (April '18)



Patient feedback I

- Arriving home I stepped out onto the veranda and for the first time in years .. birdsong! Oh bliss!!! Today at college my music lesson was a different world. (UCL)
- "I can hear sounds that I've never heard before like cars coming and birds singing" (UOA)
- "I have stopped annoying my family by having the TV very loud." (UOA)
- "I have not heard this well for 15 years." (AMC)
- "The hearing aids are, by the way, the best hearing aids I have ever had" (GST)
- "They [i.e. the HAs] have given me greater access to a world that I struggle in, which is a hearing world" (GST)

Patient feedback II (GST)

https://drive.google.com/file/d/1w2mGe3k5JTII98q_yFflUeI6TPeqqyAL/view

Next tasks: Validation of EVOTION platform as a public health policymaking tool (Leader: IPH, M27-32) I

Activity plan:

- designing a focus group (number and choice of participants, time and date, necessary equipment)
- contacting participants and informing them of the project
- trying out platform test version
- preparing questions
- preparing the questionnaire
- conducting the focus group
- data analysis
- report

Validation of EVOTION platform as a public health policymaking tool II

Participants (health policy makers, stakeholders):

- Administrative Department for Healthcare and Social Welfare of Osijek-Baranja County
- Administrative Department for Social Protection, Retirement and Health Care of the City of Osijek, Department of Health and Persons with Disabilities
- Croatian Institute for Health Insurance – Regional Office Osijek
- Croatian Pension Insurance Institute – Regional Service Osijek
- audiologists
- Association of the Deaf and Hard of Hearing of Osijek-Baranja County

T7.5 Clinical Evaluation (GST M27-33): overview

- Outcome measures: time of HA usage, satisfaction from HA usage…?
- Try to correlate these three with all features extracted from the available dataset.
- People who abandoned or used their HAs for a very limited period of time should be targeted.
- Which parameters would be interesting in being correlated to these (or other outcomes) e.g. medical history, family history, previous HA, tinnitus, existence of carers etc.
- Could extract specific questions from the questionnaires in order to correlate with outcomes.
- We can use combination of possible predictors, two or more. E.g. search for women in their 50s with moderate hearing loss and high education.
- Decide which exact combinations are of clinical interest.

Example 1: Prognosis of Effectiveness of HA Usage

Outcome measures:

- Satisfaction with HA usage – rating through the EVOTION mobile app and GHABP scores.
- HA logging data: periods of HA usage; monaural vs binaural HA use (in binaural HA users) and use of HA controls

Predictors:

- Environmental data (e.g. user location; noise; outdoor activities)
- Personal data (e.g. education; significant others; age; gender; personal carer; socio economic background; civil status)
- Behavioural data (user daily activities)
- Clinical data (e.g. smoking, diabetes, obesity, family history, ototoxicity medications, duration and type of HL, cause of HL)
- Cognitive data (e.g. MOCA scores, reaction time, forward and reverse digit recall and mood monitoring via HADS)
- Occupational data (e.g. employment history and current status)
- Physiological data (e.g. heart rate)

Example 2: Prevention of cognitive decline

Outcome measures:

- Cognitive data (MoCA, digit recall);

Predictors:

- Level and type of HL (i.e., AUD.1, AUD.2, AUD.3, AUD.4);
- Clinical and medication data (i.e., CMD.7);
- Personal data (i.e., PED.1 – PED.6) and
- Behavioural data (i.e., BHP.1 – BHP.5).
- Physiological data (i.e., PHD.1, PHD.2);

Impact of completed WP7 work

- **Progress within EVOTION:**
  - Ongoing clinical study collecting & feeding big data into the EVOTION data repository to enable the validation of the EVOTION platform
  - Completed WP7 work one of cornerstones for next reporting period work: technical, public health and clinical evaluation
- **Patient benefit:** Development of new test/training material & tools in two languages that can be used beyond end of project - already interest to use within the Greek/Cypriot communities where there is a paucity of such rehabilitation material
- **Increased HL awareness:** Strong dissemination by clinical partners to wide range of stakeholders
- **Looking to the future:** Strong engagement with several EVOTION stakeholders within WP7, including patients, clinicians and policymakers

Related projects - HOLOBALANCE

HOLOgrams for personalised virtual coaching and motivation in an ageing population with BALANCE disorders

- User centric design using Human Computer Interaction methodology.
- Holograms acting as virtual balance physiotherapists.
- New augmented reality games for cognitive training.
- Smart glasses with audio for vocal instructions and cognitive/auditory training
- Story in Noise auditory training with comprehension questions
- Capitalization on FP7 EMBalance project data and knowledge and FI-WARE generic enablers.
- Integration into a radically new virtual coach for ageing population with balance disorders.

Related projects - TACT

Treating Auditory impairment and CogniTion (TACT): a pilot trial of hearing aids for dementia risk

- Pilot trial to ensure people with hearing loss and mild cognitive dementia start and continue to use HAs
- 8-month follow-up to evaluate its effectiveness in reducing the risk of dementia
- Findings could be used to run a larger trial to determine the link between hearing aid usage and brain function.

Validation of MoCA and ACE-III as cognitive screening tools for the hearing impaired

- No good quality tests to identify whether people with hearing loss might have dementia or not.
- The purpose of this trial is to develop such tests.
- Early and appropriate detection of dementia among older adults with hearing loss is very important.
- It can help these older adults, who are at risk, to get timely intervention needed for them