NINFEA - PROTOCOL FOR THE GOLIAT PROJECT

v.1 – 23/05/2025

Sommario

1. Introduction

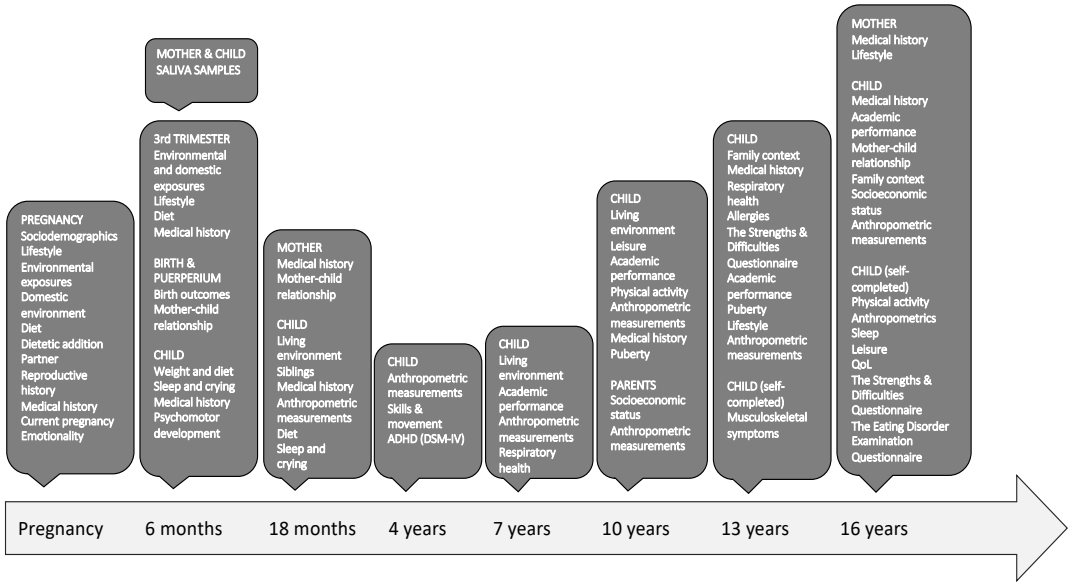
NINFEA

NINFEA (Nascita e INFanzia: gli Effetti dell'Ambiente) is one of the first Internet-based birth cohorts and the largest birth cohort in Italy. It recruited over 7,500 pregnant women between 2005 and 2016. Eligible participants were women who had sufficient knowledge of the Italian language to complete online questionnaires, had internet access at the time of recruitment, and voluntarily agreed to participate.

The study began in 2005 as a pilot in the city of Turin and gradually extended across the country. At enrolment, pregnant women completed a baseline questionnaire. Children have since been followed through a series of eight follow-up questionnaires completed by the mother when the child is 6 months, 18 months, and 4, 7, 10, 13, 16, and 19 years old (Figure 1). As of today, approximately 6,800 children have completed at least the 6-month follow-up. The number of participants at later follow-ups varies due to the dynamic nature of the cohort.

The NINFEA cohort was approved by the Ethics Committee of the San Giovanni Battista and Ospedale Maria Vittoria CTO/CRF (approval number 45, 16/09/2005, and subsequent amendments).

Figure 1. Overview of the NINFEA cohort design and data collected up to the 16-year follow-up



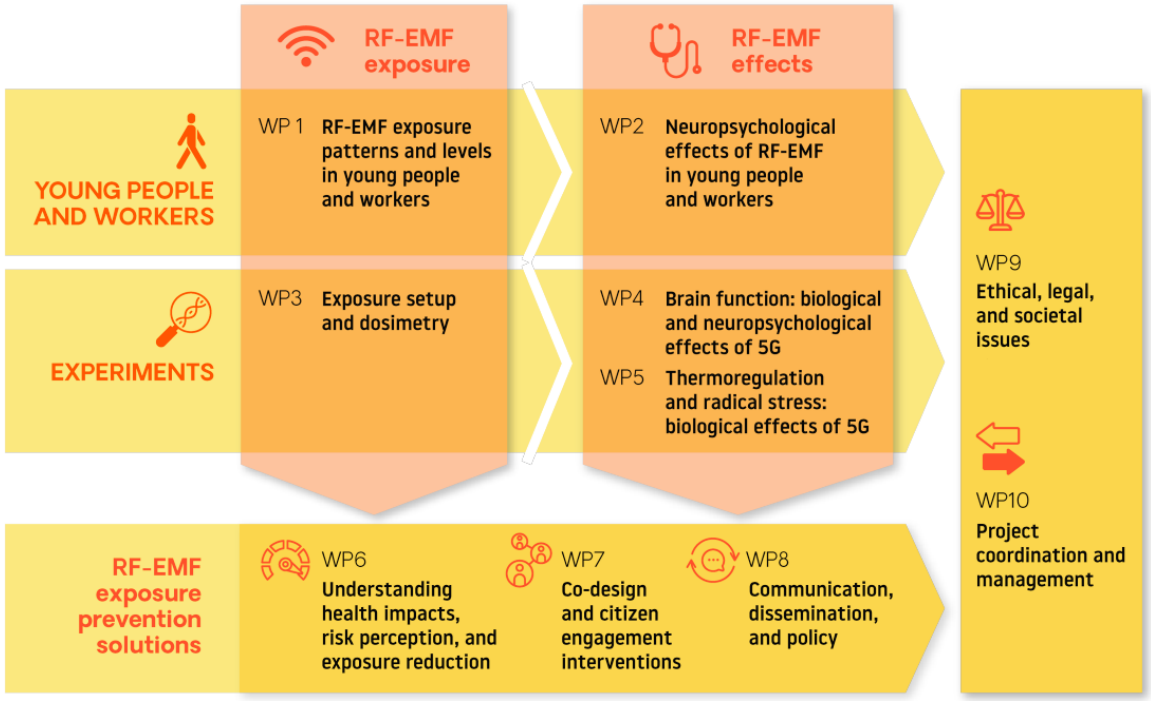
GOLIAT

NINFEA participates in the GOLIAT project (5G expOsure, causaL effects, and rIsk perception through citizen engAgemenT), a research initiative funded by the European Health and Digital Executive Agency. GOLIAT runs from June 1st, 2022, to May 31st, 2027, and aims to monitor exposure to radiofrequency electromagnetic fields (RF-EMF), particularly from 5G, investigate potential causal health effects, and explore how such exposures are perceived and best communicated through citizen engagement. One of the project's specific objectives is to assess potential neuropsychological outcomes—namely cognitive function, mental health, and sleep quality—in young people.

NINFEA contributes to this objective through the participation of two age-based subcohorts and the implementation of a structured data collection and follow-up protocol, described in the following sections.

NINFEA participation in GOLIAT was approved by the Ethics Committee of the A.O.U. Città della Salute e della Scienza di Torino – A.O. Ordine Mauriziano – A.S.L. Città di Torino (approval number CEA/45, 17/05/2023).

Figure 2. PERT diagram of the GOLIAT project



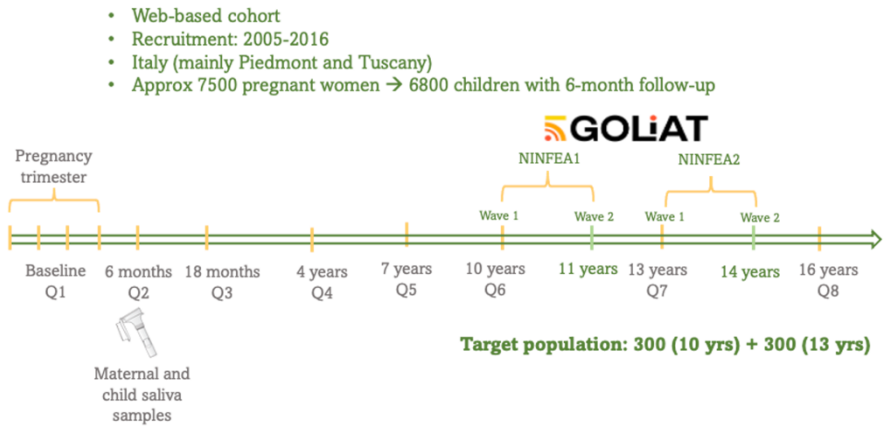
2. NINFEA Subcohorts in GOLIAT

Ten- and 13-year old subcohorts

NINFEA participates in the Goliat Project with two subcohorts: 10-year-old children and 13-year-old adolescents.
The objective is to assess the effects on sleep quality, mental health, and cognitive development of the participants following exposure to wireless technologies, with a baseline phase and a follow-up phase after one year (Figure 3).

Data are collected through two online telematic tools: questionnaire (to assess exposures, sleep disorders, and mental health) and a cognitive test (visuo-perceptual reasoning based on Raven's Progressive Matrices on a dedicated platform), as well as two physical tools: a wrist accelerometer and a weekly diary.

Figure 3. Scheme of NINFEA subcohorts participating in the GOLIAT project



3. Baseline Phase

3.1 Period

Start: October 12, 2023 – End: April 12, 2025

3.2 Eligible population

All NINFEA participants who have completed the 10-year follow-up and the 13-year follow-up in the first year of the project (period June 12, 2023 - September 28, 2024).

3.3. Invitation to the main questionnaire

Active recruitment during the baseline phase is carried out through invitations via email, phone calls, and letters aimed at encouraging the completion of the online questionnaire named *"Goliat/Exposure to Fields and Screens"*, which collects detailed information on exposure to RF-EMF, sleep, and mental health.
From October 12, 2023, and for the following 365 days, i.e., until October 11, 2024, all those who have completed the 10-year questionnaire and the 13-year questionnaire starting from June 12, 2023, receive an email invitation 15 days after finishing their questionnaire.
In case of no response after the first email invitation, a reminder procedure is followed, which included:

- a second email with the same content (10 days after the first invitation)
- a phone call (10 days after the second email)
- a letter (10 days after the phone call)

Each participant has a 6-month time window to complete the *"Goliat/Exposure to Fields and Screens"* questionnaire.

3.4 Invitation to the cognitive test

All subjects who have completed the questionnaire receive an invitation to take an online cognitive test using a dedicated software. The invitation to take the cognitive test is sent via an automatic email immediately after starting the "Goliat/Exposure to Fields and Screens" questionnaire.
This communication includes instructions for accessing the test exclusively from a PC, a personal 6-digit PIN to use as an ID to start the test, and a link to download the tutorial (which summarizes the various steps for installing and accessing the test, https://www.progettoninfea.it/attachments/104).
In case of no participation after the first email invitation, a reminder procedure is followed, which included:

- a second email (10 days after the first invitation)
- a third email (10 days after the second email)

Due to low participation in the cognitive test, a corrective measure has been adopted: starting May 21, 2024, an additional email is sent with instructions for completing the test via smartphone, aiming to overcome technical barriers identified in a small phone survey on participants who had not completed the test.

3.5 Invitation to accelerometer and diary measurements

Among all participants who have completed the online questionnaire *"Goliat/Exposure to Fields and Screens"*, a subcohort is selected and invited to participate in the collection of information on sleep and physical activity using an accelerometer, along with the completion of a diary for 9 consecutive days (from day 0 to day 8).

Participants are eligible if they have completed the *"Goliat/Exposure to Fields and Screens"* questionnaire and resided in Turin or within approximately 25 km of Turin with access to public transportation (bus/train).

Eligible participants are contacted by phone and, if interested, receive an invitation to take part in two in-person appointments: the delivery of the accelerometer and diary, attended by both the child and a parent, and the return of the materials, which did not require the child's presence.

Appointments were scheduled based on participants' availability between October 25, 2023, and January 28, 2025, partly at the Epidemiology Unit of the Dept. of Medical Sciencies (University of Turin) and partly at various locations across the Turin area to facilitate participation.

4. Follow-up Phase

4.1 Period

Start: October 12, 2024 - ongoing

4.2 Eligible population

All NINFEA participants who have completed the GOLIAT baseline questionnaire at least 12 months earlier

4.3. Invitation to the main questionnaire

Twelve months after completing the baseline questionnaire, participants receive an email invitation to complete the questionnaire *"Goliat/Exposure to Fields and Screens... One Year Later."*

In case of non-completion after the first email invitation, the same follow-up procedure used for the baseline is applied:

- A second email with the same content (10 days after the first invitation)
- A phone call (10 days after the second email)
- A letter (10 days after the phone call)

Each participant has a 1-year time window to complete the *"Goliat/Exposure to Fields and Screens... One Year Later."* questionnaire.

4.4 Invitation to the cognitive test

All follow-up participants who have completed the questionnaire receive an email invitation to take the cognitive test using the same procedures as in the baseline phase.

For cases where the cognitive test was completed with a significant delay after the baseline questionnaire, the following procedure has been adopted:

- First invitation to complete the *"Goliat... One Year Later"* questionnaire is sent:
    - 1 year + 10 days (for a delay of about 1 month)
    - 1 year + 30 days (for a delay of less than 2 months)
    - For delays greater than 2 months: participants are contacted by phone, asked to proceed with the questionnaire, but to wait before taking the test until further notice.

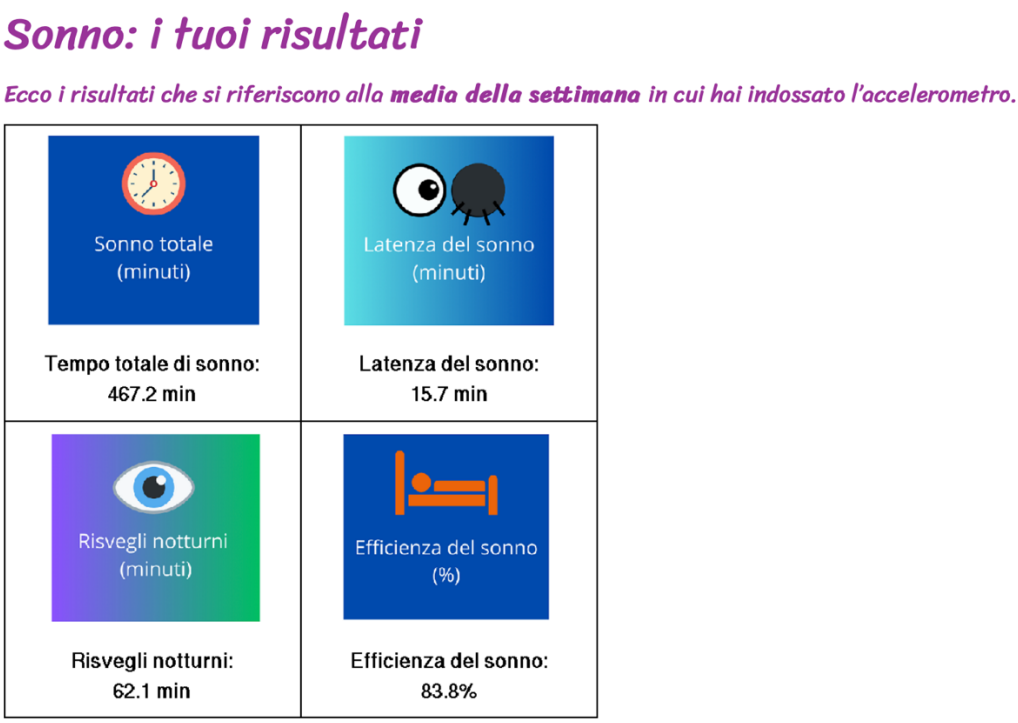
4.5 Invitation to accelerometer and diary measurements

Each participant who has at least started the questionnaire *"Goliat... / Exposure to Fields and Screens... One Year Later"* and who participated in the accelerometer and diary week during the baseline phase is invited again to participate following the same procedures.

5. Feedback to Participants

All participants who took part in the accelerometer and diary subcohort receive a personalized and concise report (newsletter) by email with feedback on the data collected through the accelerometer (Figure 4).

Figure 4. Example of the outputs of the measurements from accelerometer and diary included in the newsletter sent to individual participants



Specifically, regarding sleep, individual average measurements are provided (total sleep time, sleep latency, nighttime awakenings, sleep efficiency), along with useful tips to improve sleep quality. Regarding physical activity, the average daily minutes of moderate to vigorous activity are highlighted, together with recommendations to enhance its benefits for health and quality of life.

6. Questionnaires and other instruments for data collection

6.1 Main Questionnaire

The first part of the *"Goliat/Exposure to Fields and Screens"* questionnaire collects information about the family, any illnesses of the child, and the child's behaviors and attitudes.
In the second part, the mother is asked to complete the questionnaire alongside her child, directly asking him/her the questions in an interview format to collect data on the use of smartphones, laptops, tablets, cordless phones, and other mobile devices.

The questionnaire is divided into 15 sections, which can be paused and resumed without losing previous answers, and it takes about 15–30 minutes to complete.

The questionnaire is available at the link https://www.progettoninfea.it/tour under the title "Questionario Esposizione a campi e schermi".

6.1.1 Outcomes

The sections completed by the mother mainly concern the outcomes of interest and include:

- Family composition
- Chronic illnesses and disorders
- Mental health: Strengths and Difficulties Questionnaire (SDQ,Goodman, 1997; Italian adaptation by V. Tobia et al., 2011). The SDQ investigates strengths and weaknesses in children and adolescents aged 4 to 16 years, covering five subscales: Emotional Symptoms, Conduct Problems, Inattention/Hyperactivity (ADHD), Peer Problems, and Prosocial Behavior.
- Sleep: adaptation of the Bruni questionnaire on sleep disorders, known as the Sleep Disturbance Scale for Children (SDSC), consisting of 26 Likert-scale questions completed by parents. It is designed to assess sleep quality and identify specific sleep disorders in children aged 6 to 15 years.
- Physical activity (weekly frequency, intensity, sports)
- Device usage: perceptions of pros and cons

6.1.2 Exposures

The sections completed by the mother together with the child contain information useful for calculating the exposure of interest (RF-EMF dose) and include:

- Smartphone use (frequency and manner of use)
- Laptop and tablet use
- Cordless phone use
- Smartwatch/activity tracker use
- Use of other mobile devices
- Problematic use of the cellphone
- Restrictions on the use of electronic devices

6.2 Cognitive test

The test consists of 12 patterns of geometric figures and is an adaptation of the Raven's Progressive Matrices. It highlights analytical abilities that do not depend on previously acquired knowledge, involving spatial and reasoning skills in the solution process. The test is administered through the Millisecond platform (https://www.millisecond.com/).

6.3 Accelerometer and diary

Information on sleep and physical activity over 9 days (from day 0 to day 8) is being collected using GENEActiv accelerometers (https://activinsights.com/resources/geneactiv-support-1-1/) and diaries.
The accelerometer is an actigraph device worn 24 hours a day on the non-dominant wrist, capable of detecting movement acceleration along three axes.
The diary is a booklet completed every evening and morning, containing questions about device usage before sleep and during the night, sleep and wake times, and the perception of restfulness. The diary can be downloaded at the website https://www.progettoninfea.it/attachments/113.