Experimental Evaluation of Intergenerational Mealtime at a Shared Site: A Randomized Wait-listed Controlled Trial

Date: May 9, 2025

Study Protocol with Statistical Analysis Plan and Informed Consent Form

1. Theoretical Framework

The term Intergenerational Dining Room (IGD) refers to the intentional and planned space and experience that enables people from different generations to periodically share the experience of eating together in settings dedicated to service provision (e.g. residential centers or schools), community work, intergenerational practices, etc. The IGD conceptual approach to be piloted is based on the intersection of three key areas:

- Relationship-centered Care (RCC): scientific evidence suggests that care should focus on promoting meaningful relationships, rather than approaching people solely from an individualistic perspective of care (Gopinath et al., 2023; Kartupelis, 2020).
- Life-course perspective and feeding: the act of eating is a social practice that cuts across the life course and contributes to the construction of intergenerational relationships (Lawless et al., 2024). Previous studies have pointed to the importance of eating as a space for interaction and learning between generations (Bruce et al., 2022; Norouzi et al., 2023).
- Commensality, education and nutritional health in care spaces: research has shown that intergenerational programs have the capacity to improve the nutrition of their participants and promote healthy eating habits, especially in settings where adequate food is a challenge (Jarrott et al., 2021a, 2021b).

Despite growing interest in these approaches, empirical evidence remains limited, especially for structured IGD interventions with rigorous evaluation of their impact.

This Randomized Controlled Trial (RCT) is justified on several methodological and scientific grounds:

- Lack of robust experimental evidence: while there are observational and qualitative studies of intergenerational programs, few have used experimental designs to causally assess their effects on well-being, eating and intergenerational perceptions.
- Need for rigorous evaluation: validating the impact of IGD requires a design that allows comparison of intervention and control groups, minimizing bias and ensuring internal validity.
- Multi-dimensional impact evaluation: the aim is to analyze the effect of the intervention on aspects such as healthy eating, social well-being and health, which advised a mixed methodological approach, integrating quantitative measures (e.g., indicators of change in dietary intake and well-being) with a qualitative analysis of participants' lived experience (e.g., focused ethnography).
- Replicability: an experimentally validated model facilitates its implementation in other contexts, allowing for the development of an evidence-based implementation guide.

This trial will provide a systematic evaluation of the mechanisms and outcomes of the IGD model examined, offering a framework for leveraging this type of dining room in future intergenerational policies.

2. Objectives

The overall objective will be to assess the impact of participation in an IGD on eating, nutrition education, well-being and intergenerational perceptions in young children and older adults through a three-arm wait-listed RCT.

The specific objectives are as follows:

- To design and implement an IGD in a controlled institutional setting (Macrosad's Intergenerational Reference Center (CINTER)), ensuring the feasibility of the model and adequate interaction between generations.
- To evaluate the influence of IGD on relationship-centered care, measuring changes in the quality of the relational and social environment during mealtimes.
- To measure the impact of an IGD on nutrition education by analyzing improvements in participants' knowledge and awareness of healthy eating.
- To Determine the effect of IGD on healthy eating and well-being by assessing changes in food intake, food leftovers and subjective health perception.
- To analyze the impact of IGD on intergenerational perceptions, measuring changes in attitudes and stereotypes of toddlers about older people and vice versa.
- To validate the results and replicability of the IGD model, ensuring its applicability in other contexts through a set of implementation indicators (acceptability, appropriateness, adoption and sustainability).

2.1. Hypothesis

General hypothesis:

Participation in an intergenerational dining room is an effective means of improving relationship-centered care, nutrition education and healthy eating, generates benefits in the health and well-being of participants and promotes a more positive perception among the generational groups involved.

Sub-hypothesis (sH): Getting involved in an IGD…

sH1: improves participants' relationship-centered care and eating experience.

sH2: improves participants' nutrition education (attention and knowledge).

sH3: improves the practice of healthy eating and thus participants' subjective perception of health and well-being.

sH4: improves participants' positive appraisal of other generations, i.e. the development of generational intelligence.

Each of these hypotheses will be tested by applying quantitative and qualitative techniques in the different phases of the study.

3. Setting

The Macrosad's Intergenerational Reference Center (CINTER), located in Albolote (Granada, Spain), opened its doors in September 2018 with the aim of fostering coexistence and meaningful interaction between children aged 0 to 3, older adults, and practitioners (e.g., teachers, psychologists, physiotherapists, and so on). The center brings together under one roof a nursery school and a day center for older people, offering a unique environment designed to promote intergenerational exchange. Since its opening, the CINTER has consistently maintained high occupancy levels, with approximately 70 children enrolled in the nursery and around 40 older adults attending the day center, reflecting the strong demand and positive impact of its innovative approach.

4. Methods

4.1 Study Design

A three-arm RCT with a waiting list has been designed to assess the impact of an intentional IGD compared to a control group, minimizing bias and ensuring internal validity.

The study will include two main phases:

1) Initial intervention phase (weeks 1-8): an immediate intervention group (eating at the IGD) and a waiting group having lunch with peers.
2) Delayed intervention phase (weeks 9-16): the wait-listed group will switch to the intervention (eating at the IGD), while the control group will remain at the peer-based dining room without being exposed to the IGD.

The composition of the three groups of participants is detailed below:

Intervention Group #1 (IG1) (first stage: weeks 1-8):

- 5 so-called older friends (OF, i.e., older people from the Day Center.
- 5 so-called younger friends (YF), i.e., toddlers aged 2-3 years from the nursery school.

Intervention Group #2 (IG2) (second stage: weeks 9-16):

- 5 OF and 5 YF, equivalent to the first group, who start the intervention in the second phase.

Control Group (CG) (no intervention):

- 11 OF and 12 YF maintain their usual routine without participation in the IGD throughout the study.

Randomization is performed in a 1:1:1 ratio ensuring equal allocation of participants to groups:

- Intervention Group #1 (IG1) = 10 participants (5 OF + 5 YF)
- Intervention Group #2 (waitlisted) (IG2) = 10 participants (5 OF + 5 YF)
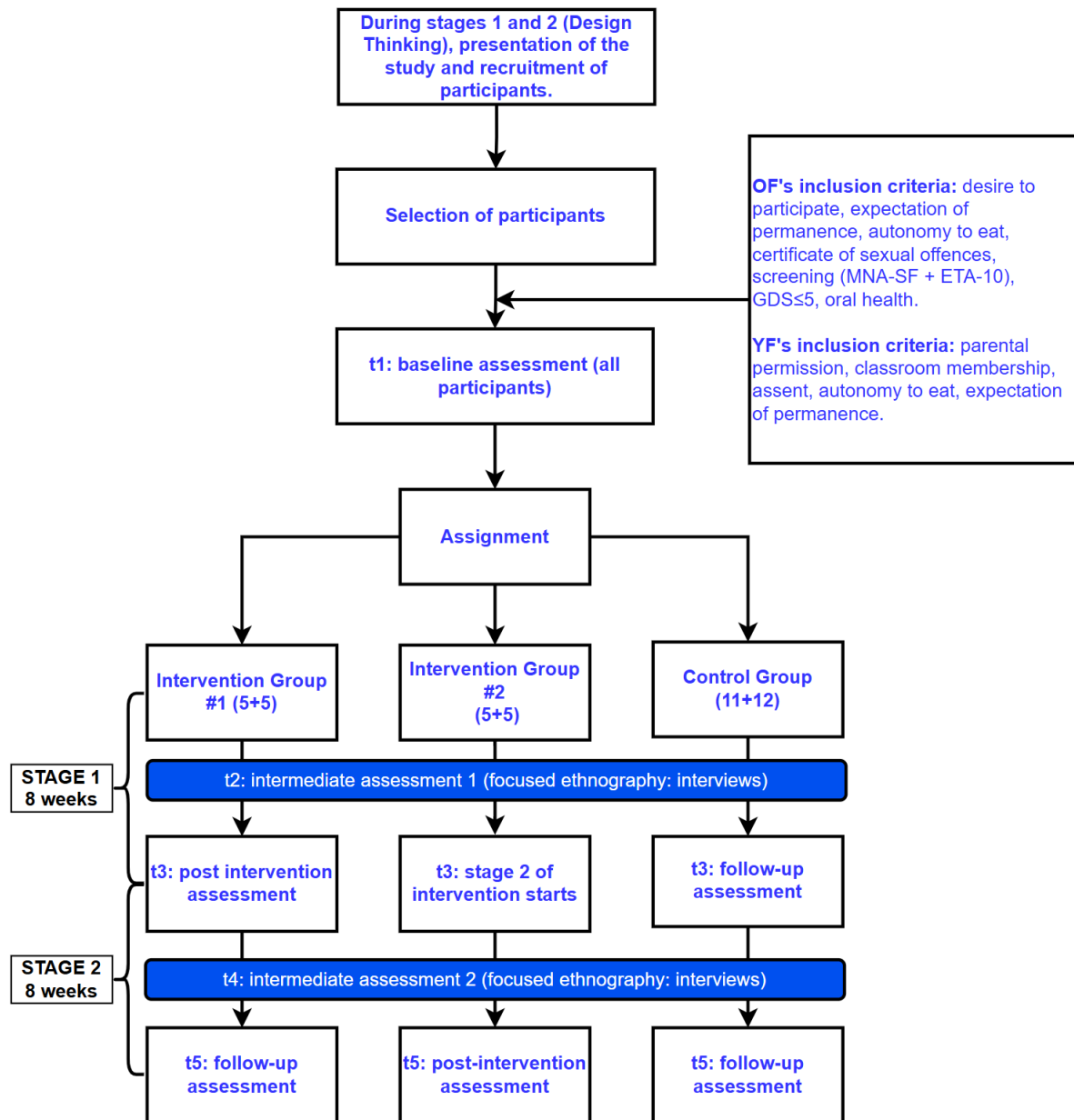- Control group (CG) = 23 participants (11 OF + 12 YF)

A computational random number generator is used to allocate participants to the three groups.

Each intervention phase lasts 8 weeks with approximately 30 lunch sessions per group. Different types of measurements are taken at five key points in time:

- t1 (baseline): Before starting the intervention (for all groups).
- t2 (middle of the first stage): Mid-term assessment in first stage.
- t3 (end of first stage): Final assessment of IG1 and pre-intervention assessment of IG2.
- t4 (middle of the second stage): Mid-term evaluation of IG2.
- t5 (end of second stage): Final evaluation of IG2 and final evaluation of the control group.

Informed consent will be obtained from all participants and their legal guardians in the case of YF. In addition, the guidelines of the University of Granada's Research Ethics Committee will be followed, ensuring compliance with ethical standards and data privacy.

Flow chart of the experimental study:

During stages 1 and 2 (Design Thinking), presentation of the study and recruitment of participants.

Selection of participants

OF's inclusion criteria: desire to participate, expectation of permanence, autonomy to eat, certificate of sexual offences, screening (MNA-SF + ETA-10), GDS≤5, oral health.

YF's inclusion criteria: parental permission, classroom membership, assent, autonomy to eat, expectation of permanence.

t1: baseline assessment (all participants)

Assignment

Intervention Group #1 (5+5)

Intervention Group #2 (5+5)

Control Group (11+12)

STAGE 1 8 weeks

t2: intermediate assessment 1 (focused ethnography: interviews)

t3: post intervention assessment

t3: stage 2 of intervention starts

t3: follow-up assessment

STAGE 2 8 weeks

t4: intermediate assessment 2 (focused ethnography: interviews)

t5: follow-up assessment

t5: post-intervention assessment

t5: follow-up assessment

4.2 Sample

The sample size for the IGD trial was determined in the framework of a three-arm wait-listed randomized controlled trial and taking into account the limitations to run this trial at the CINTER, i.e., the overall number of participants meeting inclusion criteria was small.

Intervention Group #1 (Weeks 1-8):

- 5 Older Friends (OF) from the day center.
- 5 Young Friends (YF) 2-3 years old from the nursery school.

Waiting list groups (entering in Weeks 8-16):

- 5 additional OF from the day center.
- 5 additional YF from the nursery school.
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Control group:

- 11 OF.
- 12 YF.

These figures make up a total of 43 participants (21 OF and 22 YF), selected according to specific criteria such as ability to eat independently and permanence in the center until July 2025.

They will be assessed at 5 points in time (pre-test, mid-intervention, post-test, mid-second stage and final), with quantitative and qualitative measurements detailed in the methodology.

4.3 Intervention

The interventions implemented for the two experimental groups (Intervention Group #1 (IG1) and Intervention Group #2 (IG2)) were identical in design, duration, frequency, content and implementation conditions, in order to ensure comparability of the observed effects.

Common characteristics:

- Duration: 8 weeks per stage.
- Frequency: 4 sessions per week at the IGD, with a total of approximately 30 shared meals.
- Setting: same physical space of intergenerational dining room adapted within the CINTER.
- Participants: 5 older people (OF) and 5 children (YF) per group, selected under the same eligibility criteria.
- Guided interaction: educational and care staff accompanied the sessions under a common intervention protocol.
- Evaluation: the same observation tools, scales and interviews were applied to both groups.
- The only difference between the two groups was the starting time of the intervention: IG1 started in week 1 whereas IG2 did it in week 9 (after having acted as a comparison group during the first phase).

The control group (CG), on the other hand, did not receive any intervention and continued their usual routine. This allowed to assess changes attributable exclusively to the intergenerational dining experience, while maintaining methodological consistency.

4.4 Data collection

Time Point	Evaluated Change	Instruments	Target Group	Methods
t1 (Baseline)	Food intake/waste, food preferences (Wilkinson et al., 2022), nutrition education, children's views on older adults, older adults' attitudes toward children, relational care during meals, subjective health and well-being (older adults), well-being and empathy (children)	Comstock Method(Chavez & Peréz, 2024; Egaña et al., 2023; Llorens & Soler, 2017), Ad hoc survey, Nutriplato®-based nutritional education activities (Nguyen, 2007; Termes et al., 2024), word association (Flamion et al., 2020, visual analog scale, semantic differential (Pinquart et al., 2000), Intergenerational Attitudes Scale (dos Santos et al., 2016), Mealtime Scan+ (Keller et al., 2019), WHO-5, Rosenberg's Self-Esteem Scale (Rosenberg, 1965), EQ-5D (EuroQol Research	YF, OF, YF's parents	Visual estimation, structured observation, questionnaires, interviews, scales, parent &teacher reports

		Foundation, 2024), Early Childhood Empathy Scale (Kimonis et al., 2023), Leuven Scale (Laevers, 1994).		
t2 (Mid 1st cycle)	Food intake/waste, reaction to food items, relational care during meals	Comstock Method, Mealtime Scan+, notes from observation	YF and OF	Visual estimation, structured and unstructured observation, ethnographic methods (Alcock, 2011; Knoblauch, 2005).
t3 (End 1st cycle)	Food intake/waste, reaction to food items,food preferences, nutrition education, children's views on older adults, older adults' attitudes toward children, relational care, subjective health and well-being (older adults), well-being and empathy (children),	Same as t1 plus qualitative interviews (Weltizen, 2024), notes from observation	YF, OF, YF's parents	Visual estimation, structured and unstructured observation, questionnaires, interviews, scales, ethnographic methods

	shared mealtime experience			
t4 (Mid 2nd cycle)	Food intake/waste, reaction to food items, relational care during meals	Comstock Method, Mealtime Scan+, notes from observation	YF and OF	Visual estimation, structured and unstructured observation, ethnographic methods
t5 (End 2nd stage)	Food intake/waste, reaction to food items, food preferences, nutrition education, children's views on older adults, older adults' attitudes toward children, relational care, subjective health and well-being (older adults), well-being and empathy (children), shared mealtime experience	Same as t3	YF, OF, YF's parents	Visual estimation, structured and unstructured observation, questionnaires, interviews, scales, ethnographic methods

Legend: YF = Younger Friends (toddlers aged 2–3); OF = Older Friends.

4.5 Statistical Analysis Plan

The number of participants in the trial (42 people of whom 10 toddlers and 10 seniors are expected to be part of the intervention arms while the remaining 22 (11 toddlers and 11 seniors) remain in the control group) is limited by the maximum capacity of the intergenerational experimentation center to accommodate users. Consequently, the statistical analysis will require a combination of tests depending on the distribution of the data in each case.

At baseline, various descriptive profile data were collected for both older people (e.g., sex, age, SDG level, risk of dysphagia, weight, height or calf circumference) and toddlers (e.g., sex, age, weight, height, contact with grandparents). These variables, according to their nature (binary nominal, non-binary nominal, ordinal or continuous), will be described by means of means, standard deviations, ranges, frequencies or percentages. In order to check the equivalence between the intervention and control groups, and depending on non-normality/normality, the Fisher's exact test, Chi-square test, Fisher-Freeman-Halton test, Mann-Whitney U test or Student's t-test will be applied (Shapiro-Wilk test; in case of $p > 0,05$, Student/Welch t-test may be used).

In relation to the intake of healthy foods by children and older people and given that each participant in the intervention is expected to reach about 30 meals, a mixed-effects multilevel model with group, phase and session fixation will be used. The average effect of the intervention will be the coefficient of the group x phase interaction. This type of model allows for some missing data, something very predictable in this trial, as long as that loss is random. To make sure that this is the case, the Little's test for Missing Completely at Random (MCAR) will be used. If this is the case, multiple imputation and sensitivity analysis will be applied. Post-meal leftovers data per participant will consist of mean scores after assessment by 3 investigators.The degree of inter-rater reliability will be assessed using either Kendall's W statistic (acceptance threshold $W \geq 0.70$) or Intraclass Correlation Coefficient (two-way, absolute agreement).

Regarding nutritional education and intergenerational attitudes by toddlers (semantic differential on visual analog scale) and older people (semantic differential and Intergenerational Exchanges Attitude Scale) different generalized linear mixed-effects models (LMM Gaussian) with group (intervention vs control), time (4 time points) and group x time (interaction) fixation will be estimated. With the 5 words provided by toddlers (a warm-up question before delving into the semantic differential) the frequency of occurrence and co-occurrence matrices will be calculated to see which terms appear together. Depending on the profile of these terms, an average valence score can also be carried out to see how positive or negative the sentiment expressed by toddlers is. The multiple correspondence analysis technique will allow us to represent in a two-dimensional space how these words are grouped according to time and group (intervention vs control).

The data on relationship-centered environment using the Mealtime Scan+ instrument (once due training of two raters was carried out until meeting required inter-rater reliability as measured by Cohen's Kappa (acceptance threshold $K \geq 0.70$)) will be analyzed using a linear mixed-effects model with effects fixed by dining room

(intergenerational, older people 1, older people 2, children), time (4 time points) and dining room x time (interaction to detect whether changes differ between dining rooms).

As for the subjective health and well-being data (older people), 3 linear mixed-effects univariate models will be proposed to evaluate how the subjective perception of health (WHO-5 Well-being Index and EQ-5D) and self-esteem (Rosenberg's Self-Esteem Scale) may have changed.

Finally, the statistical analysis of children's well-being, based on 9 items of the "Measure of Early Childhood Empathy" scale completed by toddlers' parents and teachers will be performed with the mean value of the two scores obtained for each toddler. Then, a linear mixed-effects model with attention to time (3 time points), group (intervention vs control) and group x time (possible change between groups) will be composed. A similar process will be followed regarding the Leuven Scale.

In each of the models, the most appropriate covariates (e.g., level of education) and confounding variables (e.g., contact with grandparents and grandchildren, respectively) will be introduced. LMM might become GLMM depending on the nature of the dependent variable at stake. The convenience of centering the continuous variables (age, baseline score) to improve the interpretability of the intercept and convergence will be considered.

Given that the study as a whole uses a mixed methodology (quantitative and qualitative), it should be noted that focused ethnography (applied, for example, to analyze the place-based eating experience, commensality and also relationship-centered care, in a different way than the Mealtime Scan+ instrument) will use qualitative analysis techniques such as thematic analysis (with NVivo support) that will take into account the longitudinal nature of the collected data.

5. Informed Consent Form

5.1 Participant Information Document

Note: the content of the document will be adapted for easy reading and comprehension by participants with different profiles.

Details of the principal investigator (PI) of the project

Name and surname: Mariano Sánchez Martínez

Center, telephone, e-mail: Faculty of Political Science and Sociology, University of Granada. Political Science and Sociology, University of Granada. Tel: 958248070. E-mail: marianos@ugr.es

Data on the project

Title and source of funding

Intergenerational Dining Room (IGD): proof of concept, prototyping, small-scale piloting and validation.

Project description

The IGD project aims to work, always within the intergenerational field, around the following aspects: (1) improving our attention to what we eat (increased sensitivity); (2) increasing our knowledge of what we eat (knowledge development); (3) living the experience of sharing a table with different generations in places where this does not usually happen (strengthening intra- and extra-familial generational intelligence); (4) the practice - or at least the observation - of relationships and mutual help between different people who eat together (promoting mutual support, care and solidarity in relation to the need to feed themselves).

To this end, the project aims to analyze and explain, for a specific institutional context - an intergenerational shared site - not only the type of feeding/nutrition but also some of the processes, causal mechanisms and impacts associated with lunchtime as a social act and intergenerational practice that connects generations in spaces where this connection takes place to different degrees and in different ways. In this way, it is hoped that feeding oneself, as a psychological, social, economic, political and cultural fact, and nutrition, as a fundamentally physiological and health-related fact, can be associated with the idea of a beneficial connection between family and non-family generations. This validated IGD model may constitute a transformative space because of its capacity to generate relational benefits for a sustainable shared life.

Data collection throughout the project will use combined procedures such as interviews, focus groups, ethnography (with image and sound collection), quantitative scales on health and well-being and analysis of nutritional habits (e.g. leftovers control, weight monitoring...). Such collection will be carried out from the beginning of the project but especially during the experimental phase (February-June 2025) consisting of a two-arm controlled and wait-listed trial.

All data collected will be anonymized, so that none of the participants can be identified, and will only be available to the project research team. This data will be deposited in an electronic archive (Drive space of the University of Granada) under the custody of the PI.

Nature, importance and expected benefits of the project

- To test whether an intergenerational dining room can enable, through appropriate interactions between generations, people to feel cared for - through the relationships they maintain.
- To appreciate food as a social act.
- To improve nutritional health and to increase appreciation of diversity and some life-course changes.
- To find out whether an intergenerational dining room might become a transformative space because of its potential to recreate a sense of 'us', away

from the weakening of social cohesion connected to a fearful and pessimistic view of community.

It is hoped that all of this will have a positive impact on participants' well-being and happiness.

Implications and risks, if any, of the research to be undertaken

In principle, and in general, the possible risks and implications derived from the research are controlled by the protocols for the protection of people set at the experimental center: the Macrosad Intergenerational Center in Albolote (CINTER).

However, specific discussions on risks and implications have been held with the people responsible for the management of the services for the older people and for toddlers at the CINTER. Conclusion of these discussions confirms that there are safety procedures already in place for the correct management of all services for older and younger clients at CINTER.

Potential use of research results

No immediate commercial use of the results is foreseen, although they may be used in academic publications and dissemination actions, including, with prior authorization, the presentation of images and videos on the development of the project. Anonymized data may be published in scientific journals, conferences, seminars, websites and dissemination channels of the University of Granada, the Macrosad Chair in Intergenerational Studies, and elsewhere.

Measures are in place to ensure adequate compensation due to any damage or inconvenience caused by the research. However, no compensation for expenses or inconvenience is envisaged.

All data will be treated anonymously and confidentially. Participation in the project in general and in fieldwork in particular is voluntary and the right to withdraw from the research may be exercised at any time without any impact onparticipants.

Confidentiality and data processing

The processing of personal data of all participating subjects will comply with the provisions of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) and Organic Law 3/2018 of 5 December on the Protection of Personal Data and the guarantee of digital rights. In accordance with the provisions of the aforementioned legislation, you may exercise your rights of access, rectification, deletion, opposition and limitation by contacting the General Secretariat by electronic means through the Electronic Register of the University of Granada: https://sede.ugr.es/sede/.

You can obtain additional information about exercising your rights in the field of data protection at the following e-mail address: proteciondedatos@ugr.es

If you consider that your request has not been answered in time or has not been adequately dealt with by our institution, you may contact the Data Protection Delegate of the University, explaining everything you consider necessary in defense of your rights, either by e-mail (dpd@ugr.es) or by post (Hospital Real, Avda. del Hospicio, s/n. 18071 Granada).

If you prefer, you can file a complaint directly with the Council for Transparency and Data Protection of Andalusia, although it is possible that this may require, prior to its reply, information from the Data Protection Delegate of the University of Granada.

5.2 Participant's consent

I, , with D.N.I. nº.

I have spoken to the professional responsible for the study.

I have read the information sheet corresponding to the project 'Intergenerational Dining Room (IGD): proof of concept, prototyping, small-scale piloting and validation', which has been given to me.

The general characteristics and the main objective of the study have been explained to me.

I have understood the research to be carried out with my participation and the use of the information I will provide, and I have had the opportunity to resolve any doubts about it.

I know that my data will be kept confidential.

I give my consent voluntarily and I know that I am free to withdraw from the study at any time and to request the withdrawal of any information I have provided up to that point.

Lack of consent at the start of the study or withdrawal of consent after the start of the study will not harm me (in any other right) or discriminate me.

I will be informed, with my consent, of the data that will be collected during the research and how this information will be obtained.

I understand that I can withdraw from the study:

- Whenever I want.
- Without having to give explanations.
- Without any repercussions for me in any way.

Additional information about the study:

- The staff working on this study have signed a confidentiality commitment with the University of Granada, so due confidentiality is guaranteed.
- Participants' data, once collected, will be anonymised/pseudonymised.

As a consequence of the above, in each case I tick one of the following boxes for consent:

Consent to participate in the study

I agree to participate in this research study and may withdraw from the study at any time if I wish to do so.

Consent to the processing of personal data

☐ YES I consent to my personal data being processed by the University of Granada. (You may withdraw your consent to the processing of your personal data at any time through the University of Granada's website: (https://sede.ugr.es/procs/Proteccion-de-datos-personales-Ejercicio-del-derecho-a-retirar-el-consentimiento-prestado/).

☐ I do NOT consent to my personal data being processed by the University of Granada.

Other consents:

☐ YES I authorise the data obtained during the research (with the relevant legal exceptions) to be communicated to me by post.

☐ I DO NOT consent to the data obtained during the research (with the relevant legal exceptions) being communicated to me.

Date:

Signature of the participant:

Fdo:

Date:

Signature of the professional responsible for the study

Basic Information on Data Protection

Responsible party:UNIVERSITY OF GRANADA

Legitimation:The University is legitimized to process your personal data because it is necessary for the fulfilment of a mission carried out in the public interest or in the exercise of public powers conferred on the data controller: Art. 6.1 e) RGPD, and art. 6.1.a) RGPD.

Purpose: To manage participation in the research study' Intergenerational Dining Room (IGD): proof of concept, prototyping, small-scale piloting and validation'.

Recipients:No transfer of personal data is foreseen.

Rights:You have the right to request access, opposition, rectification, erasure or restriction of the processing of your data, as explained in the additional information section below.

Additional information:You can consult additional and detailed information on data protection, at the following link: https://secretariageneral.ugr.es/unidades/oficina-proteccion-datos/guia/clausulas-informativas-sobre-proteccion-de-datos/info-adicional-produccion-investigadora

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