E-G-G 2023 Research Plan Template

Project title: Unveiling the Impact of Expectations on Chronic Pain: An Ecological Momentary Assessment Study

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1. Abstract

Background: Ecological Momentary Assessments (EMA) have been used to monitor pain fluctuations in chronic pain patients, identifying important predictors like anger and anxiety. Recent advances in pain research identified not only expectations but also their level of precision (i.e., how sure a person is about the expectation) as a key modulator. Despite their renowned modulatory effect, EMA never considered patients' expectations as a pain predictor.

Objectives: Outline the temporal dynamics between momentary expectation (both magnitude and precision) and subsequent pain perception in chronic pain patients (O1). Investigating the moderating effect of individual factors on the association between expectations and pain (O2).

Methods: A longitudinal EMA study will be adopted. 100 musculoskeletal chronic pain patients will be prompted 5 times daily for 14 days to complete ratings of momentary *1)* expectation of subsequent pain, *2)* confidence in expectation, and *3)* actual pain intensity.

Research plan: The project will be developed over 24 months, 13 of which dedicated to data collection at the Molinette Hospital of Turin.

Analysis: The host institution (University of Milan-Bicocca) includes researchers with strong expertise in EMA data analysis, ensuring the use of appropriate procedures. We plan to use Hierarchical Generalized Linear Mixed Models to achieve our objectives.

Expected Results and Impact: The interaction between the expectation and its level of precision will predict subsequent pain intensity. If so, the momentary assessments of patients' expectations could be used to promote precision medicine, allowing for individualised and timely strategies to break the confirmatory feedback loop that maintains chronic pain.

2. Project description

2.1 Goals of the project

Objective 1 (O1): Outline the temporal dynamics between momentary expectation (both magnitude and precision) and subsequent pain perception in chronic pain patients (O1) in real-time daily life (i.e., Ecological Momentary Assessment).

Objective 2 (O2): Examining the Moderating Effect of Individual Factors (such as Trait Anxiety, Trait Depression, Fear of Pain, and Catastrophising) on the association between expectations and pain intensity.

2.2 State of the art

Ecological Momentary Assessment (EMA) is a method that allows obtaining many measurements of a given parameter of interest in peoples' everyday life [1]. EMA allows real-time assessments in ecological settings, minimising the risk of biases linked to retrospective evaluation [1]. When working with chronic pain patients, the possibility of measuring patients' pain in their own environment is of paramount importance[2]. Thus, EMA represents a new methodological opportunity for chronic pain investigation [1]. Moreover, EMA consents to investigate the temporal relationship between pain and other momentary measures, giving insights into possible predictors which could account for the within-person dynamics of pain (e.g., oscillations between pain exacerbation and pain resolution) [1,3]. EMA has already been used to investigate the predictive value of anger, anxiety, and mood on the pain experienced by patients [3–7]. While this research is promising and valuable, we argue that a key piece is missing. EMA studies never considered patients' expectations, which is renowned for impacting pain [8–13].

Advances in pain research show that pain arises from the integration of the incoming sensory input, one's prediction of bodily harm (e.g., the expectation of physical harm following the incoming sensory input), and other context-based predictions (e.g., "I am alone so nobody will be able to help me" is an example of a negative context-based prediction)[8–12,14,15]. Overly negative predictions can result in perceiving noxious inputs as more intense, or even misinterpreting safe somatosensory inputs as danger signals, which in turn leads to experiencing them as painful [9,10,16]. From this perspective, chronic pain has been explained by a self-reinforcing loop in which pessimistic predictions (e.g., high physical harm) enhance pain, which in turn confirms the initial negative prediction, resulting in a confirmatory feedback loop that maintains pain after initial injuries have healed [17–19].

Recent evidence suggests that the extent to which the prediction (e.g., expectation) influences the percept (e.g., pain) depends on the level of precision (e.g., confidence) that is attributed to the prediction [10,16] – i.e., Expectations considered more certain influence pain significantly more than expectations perceived as less certain (Figure 1) [13,20–23]. The modulatory role of expectations precision has been mainly investigated on pain induced experimentally on healthy individuals [20–23]. The only study working on this hypothesis on chronic pain patients assumed patients' expectations precision to be constant and equivalent across individuals (e.g., everyone has the same confidence in one's expectations) without measuring it, for example, at the metacognitive level by directly asking the patients how confident they were in their expectations. It is worth noting that a recent review highlighted the need to measure expectations precision at the metacognitive level [24]. As part of my post-doctoral research, 130 healthy individuals were tested to investigate these relationships. We found that the extent to which pain perception is congruent with expectations varies depending on their level of precision (i.e., there is a greater match between the expectation and pain when the expectation has high precision), supporting the hypothesis that expectations influence pain more when these have high precision. These results are promising and winning this grant would be an opportunity for me to carry this research from the lab to the clinical setting.

Psychological traits like anxiety sensitivity, depression, fear of pain, and catastrophising have been associated with the insurgence and maintenance of chronic pain (i.e., these traits promote the formation of negative predictions feeding into the fear-based self-reinforcing loop) [25–28]. Therefore, a second goal of this project is to investigate whether these traits moderate the association between daily expectations and pain intensity pain (O2).

<u>Novelty and Innovation:</u> Despite the critical role of expectations on pain [8–13], EMA studies have so far neglected this variable in their designs. The current project aims to fill this gap **using the EMA methodology to outline the temporal dynamics between momentary expectation and subsequent pain perception in chronic pain patients.** Like pain, also expectations fluctuate and update in response to the environment. Therefore, EMA is the perfect tool to monitor expectations over time and investigate to what extent expectations can predict subsequent pain (O1). The novelty of this project is two-folded. On the one hand, it is the first time that EMA will be used to test the role of expectations as predictors of subsequent pain. On the other hand, we also include a largely unexplored candidate predictor, namely the precision of expectations. Based on the literature on healthy participants [19–22], including the research conducted by our lab, we expect that expectation precision moderates the influence of expectations on pain. Thus, the hypothesis is testing a model that is more sophisticated than the one considering expectations alone. We indeed expect that the subsequent pain intensity is predicted by the interaction between the expectation and its level of precision.

<u>Impact:</u> The project has a potentially major impact on both research and clinical practice. The successful identification of the dynamics between expectations and pain perception (O1) would allow us to identify red flags when the patient has taken the negative expectancy path that leads to pain increasing, and green flags when the patient has a positive attitude and anticipates pain reduction. Timely treatment strategies could be therefore promoted at the onset of red flags to reduce danger signals – e.g., mindful-based strategies[29,30], pain acceptance approaches[31], and safety reappraisal [32] – and to promote negative expectations re-shaping into neutral or positive ones – i.e., pain education[33] and pain reprocessing therapy[32] – while positive reinforcement strategies can be introduced during green flags (e.g., somatic tracking)[32]. <u>In other words, momentary assessments of patients' expectations can be</u>

used to promote timely strategies to break the confirmatory feedback loop that maintains chronic pain. Moreover, identifying the individual differences that render patients more, or less influenced by their own expectations (O2), would allow for more efficient precision medicine in which different strategies can be implemented depending on the characteristics of each person.

2.3 Research plan and methodology

Design: The present study is an intensive longitudinal study using EMA methodology with repeated stratified random sampling [1]. The variables sampled with EMA to achieve O1 are 1) patients' expectations towards future pain, 2) confidence in their expectations, and 3) pain intensity experienced by the patient at the time of the assessment. Situational indicators will also be collected to control for the eventual impact of specific situations [34]. To achieve O2, trait anxiety, depression, fear of pain, and catastrophising will be measured.

Participants: Patients suffering from musculoskeletal chronic pain will be recruited for the present study. A formal a priori power analysis to estimate the number of participants and observations per participant in EMA studies has yet to be reliably available. Considering the EMA literature, a safe estimation is to target at least 100 participants. Each participant will receive 5 evaluations per day for two consecutive weeks (14 days). By doing so, estimations will be based on 70 data points per patient and a total of 7.000 data points for the study. Patients will be recruited through the Molinette Hospital (Turin, Italy), with whom we already have established a preliminary agreement. All participants will meet the following inclusion criteria: male or female aged 18–70 years; suffering from chronic musculoskeletal pain, defined as persistent pain affecting muscles, joints, and bones lasting for more than 3 months [35]; average retrospective pain intensity (over the last month) of at least 3/10; having provided written informed consent [4,5]. Participants will be excluded according to the following exclusion criteria: the presence of cognitive impairment; diagnosis of psychiatric disorder, including diagnosed depression and anxiety; daily use of antidepressants, neuroleptics, anxiolytics, and opioid analgesics; being pregnant or breastfeeding, as done in previous studies [4,5,36].

Ecological Momentary Assessments: Questionnaires will be delivered using a dedicated software for EMA studies available at the host institution (e.g., Time to rate, Qualtrics). The frequency ratings (i.e., how many ratings are asked per day) and the duration (i.e., for how many days) of the study have been decided based on similar literature [1,3,5]. We will use the *stratified random sampling* method, which divides days into segments and randomly takes assessments within each segment [1,3]. Patients will be prompted 5 times per day (i.e., early morning, mid-day, early afternoon, late afternoon, evening) between 8 am and 10 pm for 14 consecutive days [3,5]. This sampling method is the most commonly used because it permits sampling at random times while avoiding uneven temporal spread and therefore providing a representative sample of respondents' lives [1,3]. At each prompt, patients will be asked to rate how much pain they are experiencing in that given moment on a Numerical Rating Scale (NRS) going from 0 = "No Pain" to 10= "Worst Possible Pain" (i.e., pain intensity). Patients will also be asked to rate how much pain they expect to experience in the following segment on the same scale from 0 = "No Pain" to 10= "Worst Possible Pain" (i.e., expectation magnitude), and how confident they feel regarding their expectation of future pain on a scale from 0 = "Not At All Confident" to 10 = "Extremely Confident" (i.e., Expectation Confidence). Patients will be asked to specify pain location(s) in all the assessment questions [3]. Additionally, we will measure the markers of situations to capture contextual information [34]. Concerning the length of the period queried, we will use the *momentary model* in which patients are asked to give their ratings based on how they feel at the exact moment they have been asked [1,3].

Trait measures: The following questionnaires will be completed by the patients at the beginning of the study: the trait scale of the State-Trait Anxiety Inventory (STAI) [37] to measure trait anxiety; the Beck Depression Inventory (BDI) [38] for assessing depression; the Pain Catastrophizing Scale (PCS) [39] to evaluate pain catastrophising tendencies; the Fear of Pain Questionnaire (FPQ) [40] to measure the level of fear associated with pain.

Procedure: After being recruited by the physician and after patients have given their consent to be involved in the study, they will be invited for their first in-person encounter with the researcher. This meeting will occur at the hospital where patients will be recruited (i.e., Molinette Hospital, Turin). During this first meeting, patients will complete the psychometric screening packet (see trait measures section). Patients will also be presented with the phone app they will use to give daily ratings, ensuring they understand how to use it.

Statistical Analysis: Analyses for longitudinal associations between measures of momentary expectations (both magnitude and precision) and momentary pain ratings will be conducted using Hierarchical Generalized Linear Mixed Models (GLMM), which accounts for within-person variability. The host institution includes multiple researchers experienced with this type of data and analyses, granting the expertise for such complex data analyses. Moreover, the host institution is fully equipped with licensed software to run the experiment.

2.4 Work plan and timeline

The first month of the project will be dedicated to writing up and submitting the Ethics Request (M1). Based on our previous experience, we expect the Ethics Committee to take approximately 2/3 months to give the approval (M2-M4). While waiting for the ethics approval, the researchers will prepare the software for EMA data collection (M2), implement the project, and pilot the experiment (M2-M4). By the fourth month, we expect to be ready for starting the data collection, which will last 52 weeks (M5-M17). Considering institutional holidays, and the summer break, we safely count on a total of 44 weeks of data collection. Recruiting, on average, 3 patients per week will allow us to include 132 patients, a sample size slightly bigger than the target of 100 that will cover dropouts. Once data has been collected, 2 months are dedicated to the analysis (M18-M19), and 3 for the preparation of the manuscript (M20 – M22). We allow two months to account for potential delays (e.g., needing an extra month of data collection) and other unforeseen obstacles (M23-M24). Within 2 years the project will be completed, and the results ready for dissemination (Figure 2).

Appendix: Figures

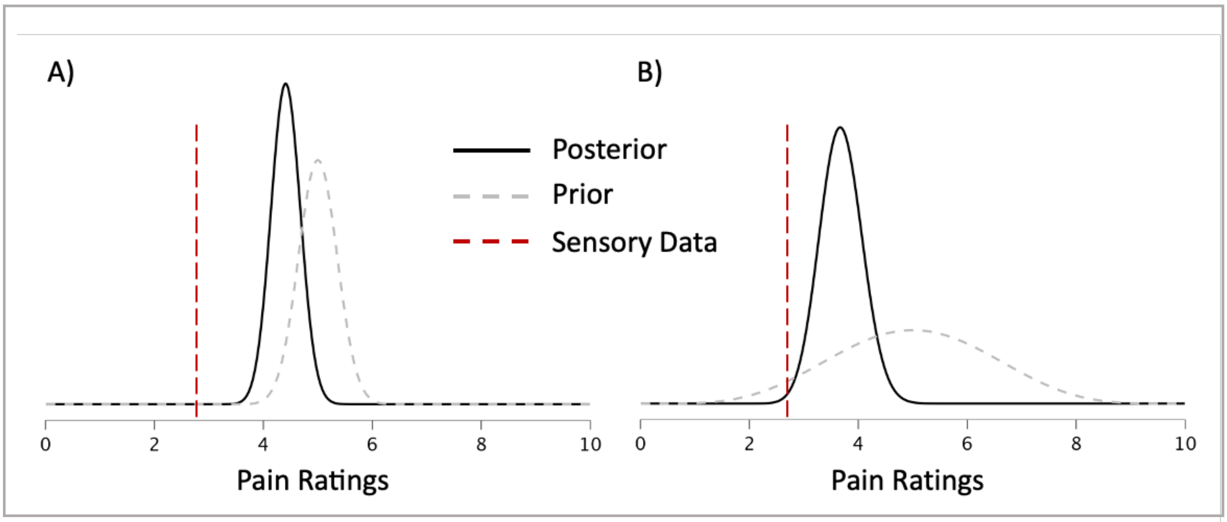

Figure 1. Pain (i.e., posterior) results from the integration between a prior (i.e., expectation), the incoming sensory data (no distribution is assumed here to simplify the graphical representation), and their level of precision. A prior with greater precision (as in the case of Fig 1 A) will have a greater influence on the pain percept than a prior with lower precision (as in the case of Fig 1 B). The same value of prior expectation (5) integrated with the same value of sensory experience (2.5) produces a different pain percept (posterior of 4.2 in Fig 1 A *versus* a posterior of 3.8 in Fig 1 B) because of the different prior precisions.

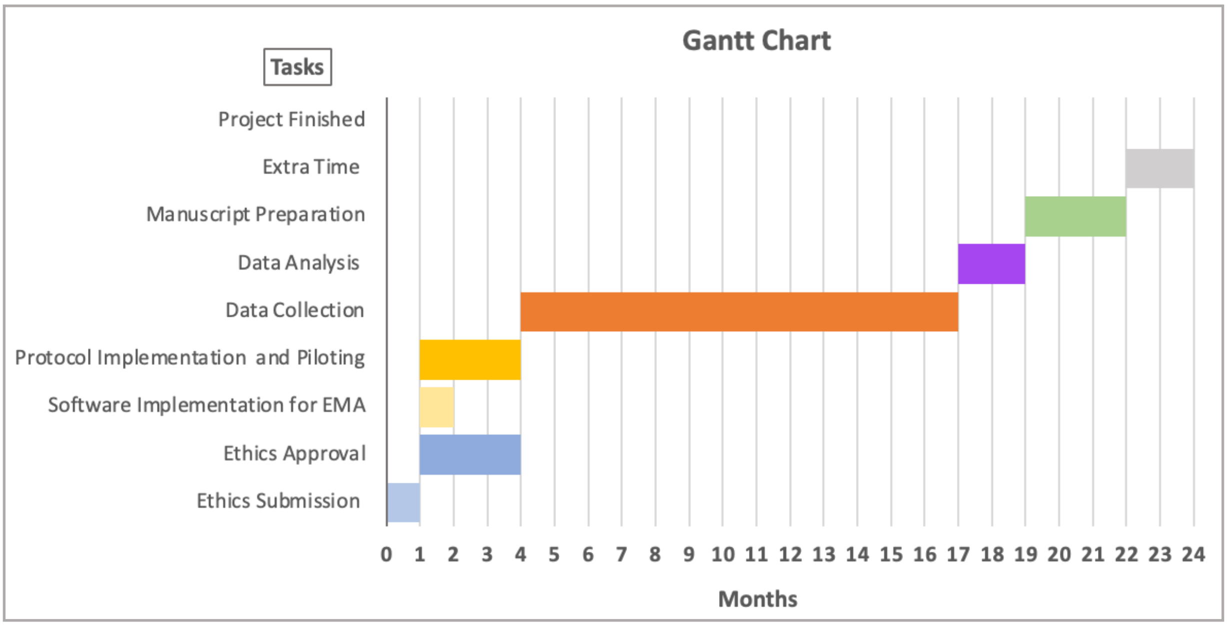

Figure 2. Work Plan and Timeline are presented with a Gantt Chart.

3. Supporting references

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4. List of Own Peer-reviewed Publications

** Denotes equal first author contribution; † Denotes equal last author contribution*.

Camerone, E. M.*, Battista, S.*, Benedetti, F., Carlino E., Sansone, L. G., Buzzatti, L., Scafoglieri A., & Testa, M. (2022). The temporal modulation of nocebo hyperalgesia in a model of sustained pain. *Frontiers in psychiatry*, 381. https://doi.org/10.3389/fpsyt.2022.807138

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