

## Study Protocol

# **Efficacy Of Modified Betty Neuman Nursing Theory to Develop Evidence-Based Pandemic Care Pathway for Preadolescents In The School**

### **Abstract :**

**Background-** A study on the effect of COVID-19 on children shows that once we pay special attention to the psychological aspect of youngsters, the worst effect occurs, although less sensitive to COVID-19. There's also evidence that nursing care supported by Betty Newman's model helps prevent 94% of patients with psychiatric cases within the medical care unit. A study that supported the appliance of the Betty Newman Systems model within the nursing care of patients with Covid-19 showed that it helps resolve the nursing problems of a patient affected by Covid-19. Supported by the above study, it's planned to develop a particular epidemic care pathway for preadolescents using the revised Betty Newman's nursing theory.

**Objectives:** To evaluate the efficacy of modified Betty Newman's Nursing Theory to develop an evidence-based pandemic care pathway for preadolescents between the experimental and control groups and associate the post-test score of preadolescents with their demographic variables.

**Methodology** -Preadolescent students will be recruited for the Superiority trial. The standard and modified Betty Newman theory will be applied to the control and experimental group. The pre and posttest of both groups will be evaluated for their effectiveness.

**Expected Outcomes:** The newly developed pandemic care approach will effectively reduce the psychological impact of pandemics in Preadolescent children.

**Conclusions:** Generation of pandemic care pathway for preadolescents and Reduction of the psychological impact of the pandemic among preadolescents.

**Keywords:** Psychological impact, pandemic, preadolescents, Betty Neuman Theory, Pandemic care pathway

### **Introduction:**

Ghosh, Ritwik, et al. studied the effect of COVID-19 on children: Focused on the psychological aspect and located the worst effect of COVID-19 on children, although it's much less sensitive. School closures, lack of outside activities, poor diet, and sleeping habits disrupt students verydaymal lifestyles and may further cause monotony, distress, impatience, irritability, and various neuropsychiatric symptoms. [1]

In the intensive care unit, Gomez T, Luz O, Diaz S, Leticia C M, Fabian A studied evidence of Betty Newman's model-based nursing care to stop dementia. Evidence has been found that Betty Newman's model-based nursing care in the intensive care unit helps prevent psychiatric cases

and has found that 94% of patients are often saved from its occurrence, also, patients with high levels of emotional distress with poor communication. [2] That. Manikandan, Ph.D. Research Scholar Tamil Nadu et al. conducted a study on stress in adolescent learners and located moderate stress between them. This suggests that the stress caused by the pandemic can increase adolescents' stress. [3] Whenever we mention children's psychological state, families often feel helpless. It can force them to approach their family doctors or find themselves within the emergency department. Doctors also struggle to attach families with their much-needed healthcare because primary care and community-based psychological state settings may or might not be an ideal link for one other.

Carlo, C, Antonioacity, et al. 2020 studied the integrated pathway: the deadly phase of the COVID 19 pandemic in central Italy. The integrated pathway is helpful in providing quality care and good results. [4] Care pathways could also be an effort to 'level up' so that individual patients and clients all receive the best standard of care. [5] Joshi P, Kumari V, and Ajeshkumar TK conducted a case study on the appliance of the Betty Newman Systems model within the nursing care of patients with COVID-19. By controlling the consequences of all stress on this patient/client system, the model proved effective in resolving COVID-19 patient's nursing problems. [6] Supported by the above study, I even have concluded that for the evaluation and counseling of the preadolescent for psychological effect, Betty Newman Nursing Theory is taken into account as the best. Pandemic stress (psychological effect) prevention focuses on multiple cares for the principle of care, but Betty Newman's nursing theory is specifically designed to treat mental stress. During this study, Betty Newman added primitive prevention as a behavioral and environmental change with entropy closure supported the current view of the pandemic as a change in nursing theory.

### **Rationale:**

Whenever we mention children's psychological state, especially, families often feel helpless. It can force them to reach their family doctors or find themselves within the emergency department. Doctors also struggle to attach families with essential healthcare because nursing care and community-based health settings for mentally ill patients may not be fully integrated. [7] That's why in Betty Newman's nursing theory, Early prevention as a behavioral and environmental improvement is added to Betty Neuman's Nursing Theory to scale back the psychological impact of the Pandemic.

The pandemic care route is accessible, efficient, and effective. More health care workers got the work of coordination to provide better and consistent care to the people. People work as partners in several health care settings and work together to make a transparent plan that shows what services and care activities are often accessed, alongside information about when and how to try to do it. That's why the care path also helps ensure that both families and care providers can navigate the mental health system more efficiently. [7] This study is meant to make an evidence-based pandemic care pathway for preadolescents. There is also evidence that Betty Newman's model-based nursing care within the intensive care unit helps prevent psychiatric cases and has found that 94% of patients are often saved from its occurrence. [2]

Nursing theory is called Betty Neuman's Nursing Theory, developed by Betty Newman. This theory is predicated on the relationship between the person and his stress and many re-establishing factors that move through nature. The Newman Systems model presents a comprehensive, holistic, and systematic approach that helps maintain flexibility in nursing. It also focuses on the particular and potential environmental stress response of patients, and therefore the stability of the client's system is maintained through primary, secondary, and tertiary preventive measures. That's why this theory has been chosen to scale back the psychological impact of the pandemic. During adolescence, the body and mind undergo many complex changes, several of which are difficult to deal with. Adolescents' physical and mental changes often begin during the first or "middle" years: ages 9 and 12. [8] Therefore the preadolescent group is chosen for the study.

Maria SFrancisca Leonetti, Italy. Found that handling quarantine may be a particularly stressful experience for folks who need to balance personal life, work, and leaving children alone within the absence of the other resources in a study on parental stress and children's psychological state problems in Covid-19 outbreak families in Italy. the shortage of support these children receive during this challenging moment could also explain their more being evidential symptoms. [9]

A Study on the Psychosocial Effect of Quarantine Measures During Outbreaks of Severe Corona Virus: a fast Review and located that in 13 identified studies, different measures resulted in adverse psychological outcomes with persistent depressive symptoms, anxiety, anger, stress, posttraumatic stress, social Isolation, Loneliness, and stigma. [10] Outbreaks appear to be exacerbated during this point, but psychological effects are more pronounced, especially in preadolescent children. Therefore, the psychological effect is usually taken under consideration.

As the concept of entropy results in illness [11] is not required, Betty Newman Nursing Theory is closed to specializing in reducing psychological impact by adding primitive preventive measures within behavioral and environmental change.

### **The explanation for the choice of comparators**

1. Betty Newman's system theory helps reduce stress between the individual and, therefore, the environment. [12]
2. Betty Newman's system theory aims to scale back the psychological impact of pandemics by adding primitive prevention and improving it after extensive improvement within the preadolescent.
3. As an ancient remedy, emotional intelligence proved to help reduce stress. [13]
4. A Pandemic care pathway supported structural evidence is required to stop the psychological impact of the epidemic in children. [14]

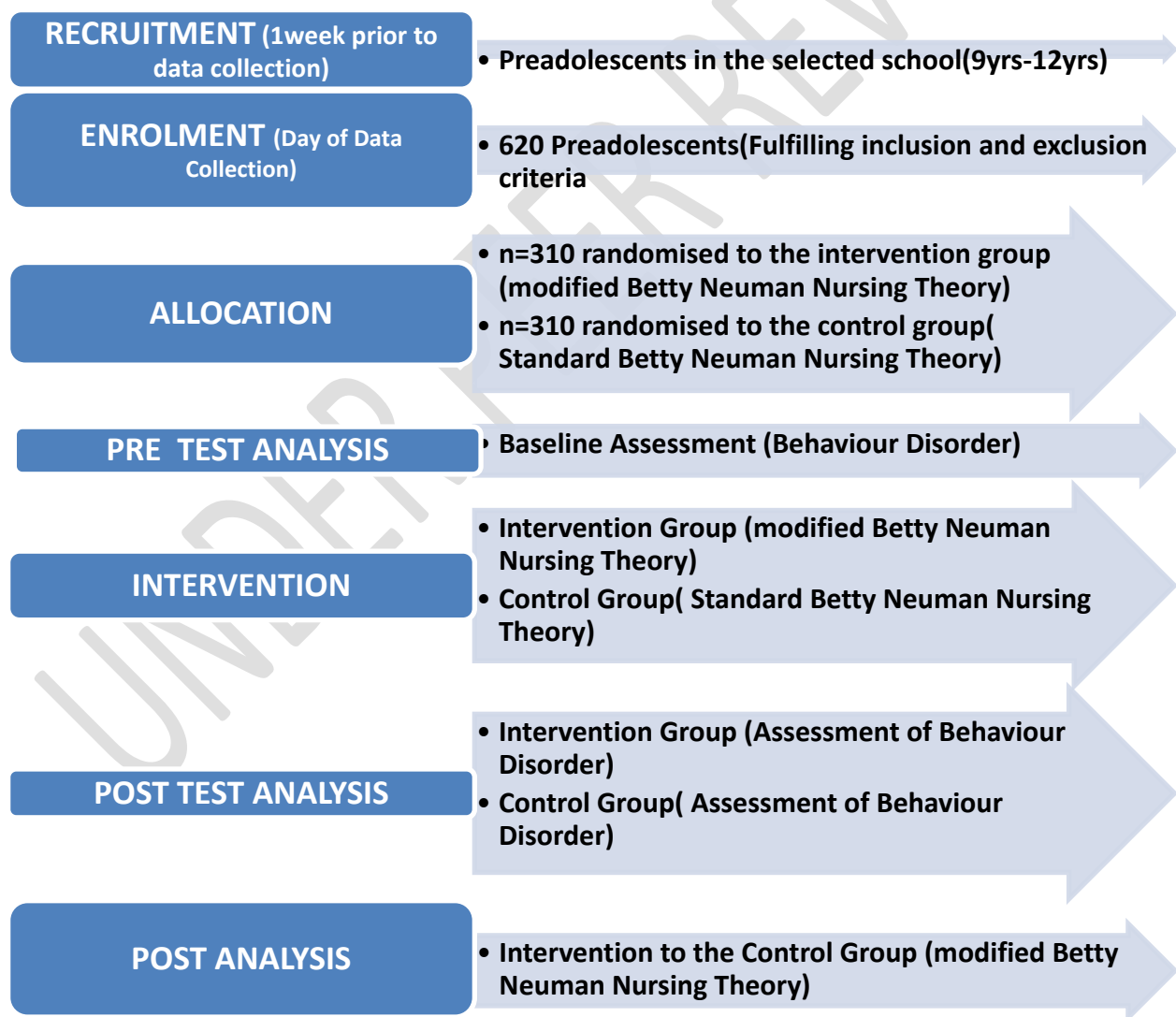
5. Preadolescents are badly affected during pandemics , as physiological changes at this stage increase stress, so this age is chosen for the study closing the concept of entropy. [15]

**Objectives:**

1. To evaluate the efficacy of modified Betty Newman’s Nursing Theory to developan evidence-based pandemic care pathway for preadolescents between experimental and control groups.
2. To associate the post-test scores of preadolescents with their demographic variables.

**Trial design:** randomized controlled superiority trial, parallel-group, two arms with 1: 1 allocation ratio. [16]

**Pic 1. Study Framework:** - [17]



**Methodology:**

**Study setting:** This study will be conducted in selected middle schools around Wardha, Maharashtra, India.

**Eligibility Criteria:**

Inclusion Criteria: -

1. Preadolescents whose parents give consent.
2. Preadolescents who meet the regulation (9 years - 12 years)
- P. Preadolescents are studying within the school chosen for study.

Exclusion Criteria: -

1. Preadolescents not present at the time of data collection.
2. Preadolescents with acute illness, mental disability, or disability.

**Interventions:**

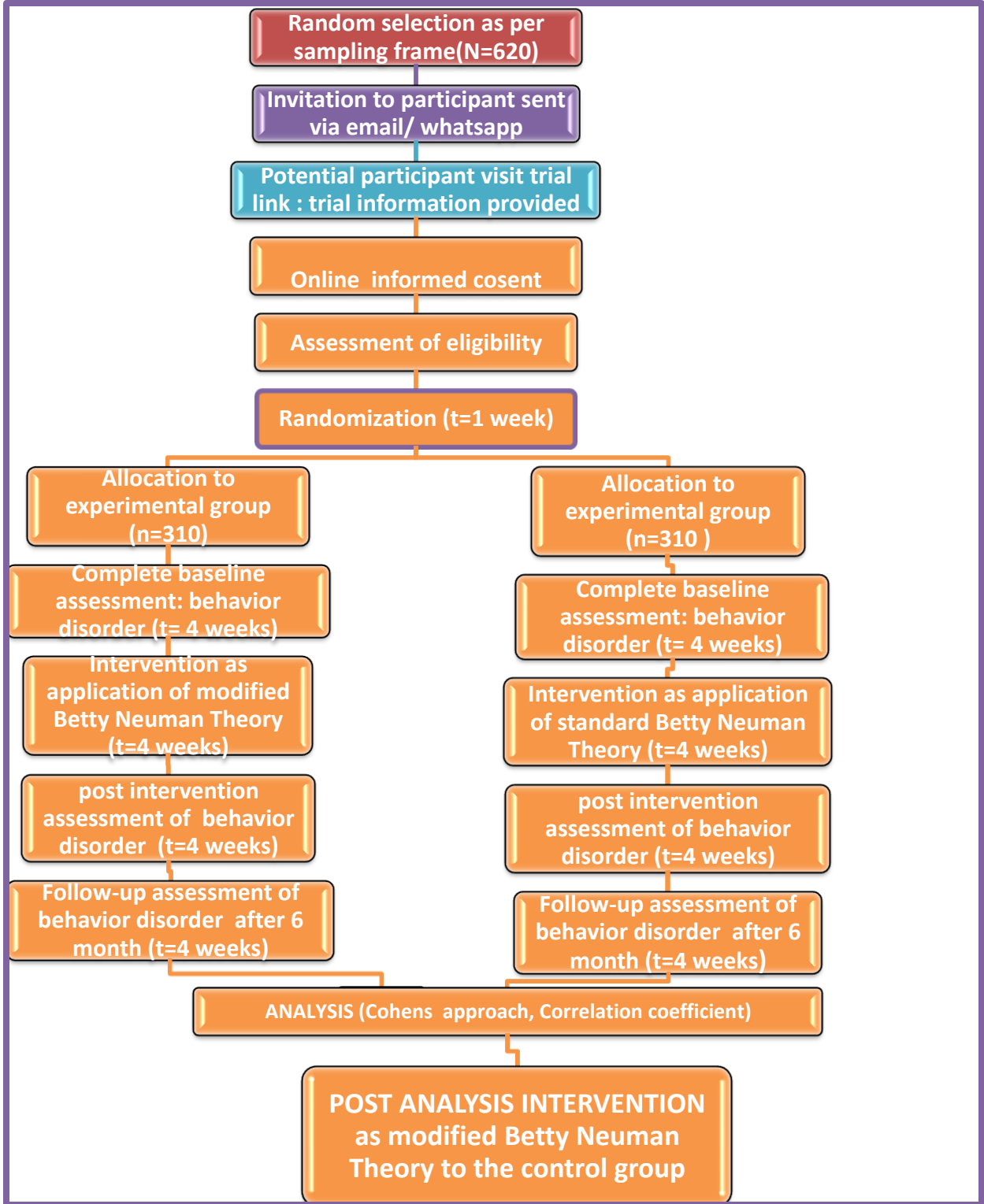
- \* Modified Betty Newman's system theory within the experimental group (primitive, primary, and secondary prevention with the concept of entropy closed).
- \* Standard Betty Newman's system theory within the control group (primary, secondary and tertiary prevention).

**Result:** After two years of study

Primary: - Generation of structural evidence-based pandemic care pathway for preadolescents.

Secondary: - Reduction in the psychological impact of the pandemic among preadolescents.

Participant timeline: - it's represented by a schematic diagram. [18]



Pic 2. Study protocol

**Sample Size:** After a pilot study with a minimum of 100 samples in each group: The experimental and control group sample size will be estimated for the main study. [18]  
**Recruitment:** Random allotments are going to be made  
**Methods:** Assignment of interventions (for controlled trials): [19]  
**Allocation:** Sequence generation-by class roll numbers of students  
**Allocation concealment mechanism:** The mechanism of implementation of allotment sequence by allocating two groups as an experimental group as A and control group as B and A are going to be allotted to those having odd numbers in sequence and B are going to be allotted to those having even number in the sequence.  
**Implementation:** With the assistance of the student's class teacher, the Chief Investigator will generate the order of allotment. The teacher or Chief Investigator will register the participants. Therefore, the Chief Investigator will assign participants for intervention.  
**Blinding (Masking):** during this study, participants will be blinded by the tactic of concealing the acceptable allotment. Therefore, the result assessment will be blinded by allowing random assessment.

#### **Data collection, management and analysis methods:**

Data Collection Methods: an outline of assessment and outcomes, plans and study tools for the gathering of baseline and other trial data (e.g., questionnaires, including any related processes to promote data quality (e.g., duplicate measurements, training of assessments). Laboratory tests)) with their reliability and validity, if known. A reference that data collection forms are often found if not within the protocol.  
Plan :-Theplan to promote participant retention and full follow-up includes an storage of any outcome data collected for participants who pack up or deviated from the intervention protocol.

Data Management: Schemes for coding through SPSS package and data entry through computer memory

Statistical methods: Cronbach's alpha for tool reliability [20], statistical significance by superiority trial [20,21], coefficient of correlation for association.

Definition of analysis Population: preadolescent is that the analysis population and of statistical procedure to manage missing data by experimental and multiple impulses[22].

Data Monitoring: Data monitoring are going to be done under the guidance of statisticians.

Harmful: No harm from the study but a modified Betty Newman Theory to the control group are going to be given as a post-analysis intervention for ethical consideration.

Auditing : Trial conduct, if any, by pilot study, and therefore the process won't be independent of investigators and sponsors.

#### **Ethics and Dissemination:**

Research Ethics Approval: IEC Approved

Protocol amendments: Significant protocol changes (e.g., changes in eligibility criteria, results, analysis) are planned to be communicated to the parties concerned within the trial registry.

Consent or assent: consent or assent are going to be obtained from potential trial participants or authorized surrogates through Google Online Forms.

Confidentiality: Personal information about potential and registered participants are going to be collected by Google and coded to judge confidentiality before, during and after the trial.

Declaration of Interests: Financial and other competing interests for principal investigators for the general trial are going to be self and site of the study are going to be selected schools of district Wardha.

Data: Access: The PI will have access to the ultimate trial dataset, and there's no disclosure of an agreement that might limit such access to investigators.

Ancillary and post-test care: The modified Betty Newman theory are going to be interfered with within the control group post-analysis.

Dissemination Policy: Test results by investigators and sponsors are planned to be distributed to participants, healthcare professionals, the overall public and other relevant groups through publication and reporting of leads to databases.

### **Expected Outcomes / Results:**

- I. Generation of structural evidence based pandemic care pathway for preadolescents.
- II. Reduction in psychological impact of pandemic among preadolescents.

### **Discussion:**

Joshi P, Kumari V, and Kumar TK found that by applying the Betty Newman nursing care model, a case study on the nursing care of Covid-19 patients could effectively solve the nursing problems of Covid-19 patients through Betty Newman nursing care . [6] . Therefore, Betty Newman's System Theory has been chosen to scale back the psychological impact of pandemics in preadolescents.

Gómez T, Luz O, des S, Italy. supported the evidence and Betty Newman's model, did a study on nursing care to stop dementia within the intensive care unit [23] by controlling continuous noise and artificial light through the Guidein nursing care . Poor communication also causes high levels of emotional distress in patients. Therefore, so as to urge a for better approach in reducing the psychological impact of the pandemic during and after the pandemic prevalence, primary prevention is added within the model as a modification. Jean H. Brody, Steven M. Kogan, Yi-Fu Chen et al. Conducted a study on children problems assessing the long-term effects of a program of strong African American families. The prevention effects were stronger for children at greater risk of developing behavioral

problems [24]. Therefore, within the current scenario, primitive prevention has been added as a change in Betty Newman's system theory to stop the psychological effects of the pandemic in preadolescents.

Jean H., Steven M. Cogan, Yi Fu Chen et al. founded that the participating adolescents reported significantly lower behavioral problems, substance use, substance use problems, and depressive symptom frequency supported the study between the initial and long-term assessments of the study compared to the controlled condition over a 22-month period. , Problems and depressive symptoms in black adolescents. This study showed that the preadolescent care pathway wasn't included in any of the studies [25]. Thus, this group has been selected for the study to develop an pandemic care pathway. Kumar S and Shilpi found low adherence to quarantine so a study has raised serious concerns about preventive measures to realize the effectiveness of quarantine in children and adolescents due to the Covid-19 pandemic on a study Compliance and Psychological Impact of Quarantine in Children and Adolescents via Covid-19 Pandemic. Adherence and psychological state problems are often improved by providing adequate support and advanced knowledge about pandemic planning [26, 27]. This study shows insufficient awareness of the pandemic. This gap are going to be bridged by educating both the preadolescent and their relations through primary preventive measures. Gaisoum, Salem B, et al. found Mental disorders like post-traumatic stress, depressive and anxiety disorders are proven to occur, also as grief-related symptoms resulting from the COVID-19 pandemic in one study if adolescents have a mental disturbance during the COVID-19 pandemic and lockdown. Adolescents with a mental disturbance may experience increased symptoms via a breakdown or change in their care and management. The COVID 19 pandemic and therefore the lockdown may have a negative impact on the psychological state of adolescents, although there are not any data yet on the long-term effects of this crisis. [4.] This study shows that structural evidence-based care must be developed to scale back the psychological impact of pandemics in children. Jessica N of Nursing Theories. Baker's comparison theory uses prevention as a basis for promoting health and provides a holistic and comprehensive approach to maximizing consumer health by locating towards the stresses that affect the connection between client and therefore the environment [22]. Betty Newman's theory doesn't shed light on primitive prevention which might be more beneficial if added. Therefore, adding primordial prevention as a precautions in theory can reduce the psychological impact of the pandemic during and after its prevalence. A number of studies related to Covid pandemic were reported[28-30]. Some of the related studies were reviewed[31-34].

### **Conclusion:**

Generation of pandemic care pathway for preadolescents as they're the vulnerable group for getting worse psychological impact in the pandemic and hence are often prevented to much extent.

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