

Major Methodological Challenges in Clinical Study of Qigong Practice as a Therapy

气功修炼治病的临床研究之方法论挑战

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ABSTRACT

Scientific research of Qigong therapies is very recent, which has generated some interesting findings in medical literature. However, a cursory reading of some research studies or systematic reviews may lead us to conclude that Qigong therapy is promising but lacks solid evidence. To date no firm conclusions as to the health benefits of Qigong therapy may be drawn based on extant clinical evidence due to the numerous weaknesses and methodological flaws in many clinical studies. This presentation will reveal the major methodological challenges in conducting quality clinical study of qigong practice as a therapy, including issues like a compatible control, a suitable qigong form for clinical practice, feasibility and acceptance, standardization of the therapy, monitoring the compliance, dosage, and length of observation. In order to have more quality research done in mind-body exercises and qigong therapy, we must learn more about the characteristics of Qigong forms and their underlying mechanisms before we can design valid randomized controlled trials that determine their feasibility and efficacy for specific health conditions.

Scientific research on Qigong or Qigong therapies is very recent, but it has generated many interesting findings in medical literature. However, a cursory reading of some research studies or systematic reviews may lead most readers to conclude that Qigong therapy is promising but lacks solid evidence. To date no firm conclusions as to the health benefits of Qigong therapy may be drawn based on extant clinical evidence due to the numerous weaknesses and methodological flaws in many clinical studies. These weaknesses include small sample size, faulty research design such as lacking or poor randomization or blinding, poor trial execution, reporting bias, incompatible controls, insufficient detail on therapy standardization, and a lack of repeatability.

I am fortunate to have had the chance to conduct some exploratory studies on Qigong therapies, both self-practice and external Qigong therapy, in collaboration with some remarkable Qigong healers and established scientists. Here, I will briefly discuss some of the common methodological challenges that must be addressed when conducting clinical study of Qigong practice as a therapy, and offer some suggestions for researchers engaged in this fascinating area of life science.

A. Know What You Are Studying

Qigong practice and meditation training are the main components of medical Qigong, which refers to individual self-practice of various Qigong forms under the guidance of a teacher or qigong healer. Qigong practice may be either dynamic with choreographed physical routines (Dong Gong), or static with mostly meditation, Jing Gong. Movement forms of Qigong and static meditation each has its own challenges when designing clinical trials in modern medical research, in which double-blind, placebo-control, and randomization are the gold standard, but very difficult to be implemented in study of qigong practice.... More importantly, most Qigong forms were developed as daily health and mind-body practices, not as a therapy for specific diseases. Therefore, when researchers try to apply the conventional methods of clinical trial to the study of Qigong's therapeutic effects, they must adapt their methods and logic to the requirements of the unique modality, Qigong therapy. Although it is impossible to do a double-blind placebo-controlled trial on Qigong practice like those performed on psychotherapy, we can improve research design and make the resulting data more acceptable to the scientific community if we are clear about the differences between study on Qigong and that on other therapies.

It will help greatly with research design if the researchers know a little about how Qigong therapy works. Although its mechanisms are still the subject of scientific exploration, we have some idea as to how Qigong practice produces beneficial effects. Its main therapeutic properties appear to lie in its ability to regulate the respiratory system, metabolism, cerebral cortex activity, central nervous system, cardiovascular system, and abnormal organ reactions. It massages the organs of the abdominal cavity and enhances one's control over the physical functions of the body. According to traditional Chinese medicine (TCM) and the available scientific literature in Chinese, Qigong healing acts through the following pathways:

- a. Qigong practice increases Qi flow in the meridians, removing Qi blockages and areas of unbalanced energy, which, according to TCM theory, cause sickness and pain. Qi imbalance is the precursor of any physical illness; an important way to stay healthy is to keep the Qi flowing smoothly in the body so that each cell in the body gets a constant supply of vital energy. Once the supply of Qi to the cells becomes blocked, blood flow to that area will change, and disease or pain can occur. One way to use Qigong therapy for pain relief and symptom reduction is to motivate qi and energy, breaking the blockages and rebalancing the energy system. Thus it is common for Qigong practitioners to report a temporary increase in symptoms or pain as Qi moves against blockages. These symptoms disappear completely with continued practice.
- b. Qigong practice might detoxify unhealthy qi and unblock meridians. Many Qigong exercises are designed specifically to drive unhealthy qi from the body via the affected channels, thus reducing symptoms and balancing the Qi of the body.
- c. Cultivation of Yi and the emphasis on an "empty mind without desire" can help practitioners develop a detached attitude toward stressors, strengthen their will power, release suppressed emotions, and resolve mental disturbances. Many chronic diseases of unknown origin might well be related to mental disturbance, social pressure, or emotional blockage. Qigong practice can allow the release of such disturbances. It is a common for Qigong practitioners to tear up, cry, or laugh during Qigong practice

and feel complete relief afterward. In addition, the increased power of a focused mind and an enhanced level of intention might, like guided imagery, work with the body to address and normalize illness (He, 2003; Chen, 2004). Scientific evidence from parapsychological studies suggests the potential of Yi although we do not know exactly how it works (Shao et al. 2009).

- d. Qigong practice uncovers or recovers the body's self-healing capabilities, including immune function and regeneration (Chen & Yueng, 2002; He, 2003). The relaxation and tranquility achieved during Qigong practice can relieve stress and build up vital energy as well as immunity (Lee et al. 2001); and some data connect relaxation and guided imagery with increased immune function, while connecting stress and depression to immune system malfunction. We have observed many patients who have completely and quickly recovered from multiple symptoms and complex diseases with Qigong therapy without any medication as well as middle-aged adults and elders who have experienced such things as new hair growth. Qigong therapy has the potential to challenge current medical reliance on symptom-suppressing pharmaceuticals.

Once the researchers know the basics of Qigong therapy, the issues in research design will be easier to be understood.

B. Dealing with the Specification of Qigong Therapy

The following are challenges that commonly arise in the study of Qigong, including movement Qigong, Taiji, Reiki, mindfulness, and other forms of meditation.

1. A Compatible Control Group

Although placebo control is not mandatory in a study of Qigong therapy, an appropriate control involving a similar commitment of time and attention and parallel outcome measurements at the same time points is both necessary and challenging. A common control is the wait list: researchers recruit the required number of participants and randomly assign them to immediate treatment or to a wait-list control group that will receive Qigong training later. This design is convenient but not convincing in outcome. Since the wait list control subjects commit no time and get no attention while the immediate treatment group is in training, a difference in outcomes would reflect not only the benefits of Qigong practice but also the benefits of committing time to the Qigong class, homework, and home practice, of getting the extra attention of the instructor or doctor, and of the expectation of improvement conferred by a new therapy regardless of its efficacy. These elements must be considered when constructing a good control group. I have no final answers to this challenge but can offer examples of good designs that might be useful when conditions are suitable:

- a. Education control. Control subjects will meet in group or individually, depending on the design of the active Qigong group, for facilitated study of pre-designed materials related to the disease being treated. This will give enough information to interest them in the study process but no practice

or actual consultation. They will meet for the same amount of time and at the same frequency as the active Qigong group. Their homework can be additional readings or video programs that require time, commitment, and attention and a level of expectation equivalent to that the active group.

b. Supportive counseling (SC), also known as non-directive therapy. SC may be delivered individually or in group. In SC the trained therapist refrains from directing the client but instead reflects what the client has said, sometimes by restating the remarks. SC has been used as a control in therapy development studies and psychotherapy research, and proved to be effective in providing non-specific effects such as therapeutic alliance and therapist competency that can contribute to outcomes. However, SC might have a therapeutic effect on anxiety. With SC as control, Qigong and control groups will receive therapy interaction with similarly structured meetings or instructions. Subjects in both groups will be assigned respective homework: Qigong practice or journal writing.

c. A special activity that takes time to learn and practice but has minimal or no obvious health benefits. This control might require extra creativity and time to verify that it is inert. An example is a new game that requires group interaction and instruction similar to that in the Qigong class but lacks mindfulness or mind-body integrative exercise.

d. An alternative active treatment. Qigong therapy might be compared to existing exercises or alternative therapies that require a similar time commitment and have a similar instruction structure. The outcomes of such comparison must take the benefits of existing therapies into consideration. For example, physical exercise (Frye et al. 2007; McMillan et al. 2002; Oken et al. 2004), pharmaceutical therapy (Li, Chen & Mo 2002; Gross et al. 2011), music therapy (Stein et al. 2010), progressive muscle relaxation (Schmidt et al. 2010; Smith et al. 2007), an established rehabilitation program (Wang et al. 2010), and a corporate stress management program (Sheppard, Frank & John 1997) have all been used as control in studies on the health benefits of Qigong, Tai Chi, Yoga, mindfulness, and other meditative therapies. Most of these studies have shown Qigong or the meditative therapy to be as good as the known active comparison; some even show significantly better outcomes for Qigong than for the active therapy control (Li et al. 2002).

2. Selecting a Suitable Qigong Form

There are thousands of different Qigong forms or schools. It is always a challenge to select an appropriate form of Qigong for research study. If you ask a Qigong master what disorders his Qigong form addresses, the typical answer will be, "My form is good for any health condition when practiced properly," or "My form does not treat specific diseases but returns balance and harmony to the body." But from the history of Qigong we can easily see that all Qigong forms are not the same. Although all Qigong forms have some health benefits, and especially for stress management, most were not developed especially for health and healing. Buddhist (the largest Qigong tradition in China) and Confucian Qigong are focused mainly on purifying the mind and cultivating spirituality; martial arts

Qigong on fighting and defense. Only medical and some forms of Daoist Qigong concentrate on health and healing.

How can one tell that a Qigong form is appropriate for a specific health condition? One cannot unless it has been studied. Before choosing a form that has not been documented as effective for a specific condition, the researcher must do some homework before rushing to a RCT; resources are limited in our field. One might start with a case study or join forces with a specific Qigong master. Here is a list of things to be considered when selecting a suitable form:

- Number of successful cases that have been documented or confirmed
- Previous published clinical studies using the form
- Availability of a capable Qigong instructor or master for consultation or training in the form
- Ideas about potential mechanisms that recommend the form for the specific health condition: Knowing the basic mechanism will definitely help; if you do not know the mechanism, you need other information to justify your decision.
- Was the form designed for this kind of health condition, or does it simply promote health and restore balance? Most forms designed to restore balance and harmony take much longer to learn and thus might not be suitable for the study. See more discussion on feasibility and acceptability to patients below.
- Potential for use in standard therapy or as intervention: The ultimate purpose of the research is to develop a feasible and beneficial therapy.

3. Test of Feasibility and Acceptance

Having selected a suitable Qigong form, some researchers would like to initiate an RCT immediately, for career or other reasons. But because most Qigong forms are intended for individual daily practice, not therapy in clinical settings, the chosen form might need to be modified to suit clinical and patients' needs and capabilities. Qigong practice requires commitment both in time and physical effort. No matter how powerful the form, it will not work in a clinical trial if it is unsuitable for the patients. Researchers might consult with Qigong instructors and practitioners, healthcare professionals, and patients in order to adapt the form. An open pilot trial with the adapted form will allow the investigators to determine feasibility and acceptance and get preliminary data on effect size and outcome measures for an RCT.

One particular medical Qigong form has produced some amazing and miraculous outcomes in cancer patients in China. I tried to design a clinical trial on this form for cancer patients in the U.S. But during the initial stage, the master who created this form insisted that the patient must practice it four or more hours a day in order to achieve the expected outcomes. It is very difficult for late-stage cancer

patients to spend that much time in Qigong practice, so this form was not feasible for the trial. Excellent for those able to commit to it, it is suitable for case studies, unsuitable for an RCT.

Mindfulness-Based Stress Reduction (MBSR) is a very powerful standardized meditation program that has been used in many clinical studies for its health benefits. However, I read some reports by researchers who tried to use unmodified MBSR in prison and in treatment facilities for adolescent drug addicts. This program is an unlikely fit for such subjects; many ordinary adults and college students find the MBSR's 8 weekly 90-minute meetings plus half-day retreat and weekly homework difficult to sustain. In the MBSR pilot study for adolescents in addiction treatment, only 5 out of 9 participants reported practicing after the training class and 2 planned to practice it in the future. This is not a good outcome for a therapy that requires continuity and commitment. No matter how effective a Qigong form is in a clinical observation, if it is not feasible for your patient population, it is not suitable for an RCT.

4. Standardization of the Therapy

Historically, Qigong has been practiced individually with one-on-one instruction from a master because each student responds differently to practice and energy flow. Group practice is recent. This brings us back to the issue of standardized versus individualized therapy. Mind-body modalities such as Yoga, Reiki, and MBSR, which have gained popular recognition from mainstream medicine even though they may not be ideal therapies for everyone, probably owe their success to their standardization and to their operational manuals. After a pilot feasibility study is done, standardization is the next step toward launching a clinical study. Without standardization and an operational manual, it is almost impossible to introduce Qigong practice into a clinical setting, since it is impractical to train enough qualified instructors that can deliver Qigong therapy properly and in a short period of time. Besides, the really powerful qigong practice is supposed to be very simple (越是高功越简单).

The National Institute on Drug Abuse (NIDA) has developed grant guidelines on this, (*Behavioral & Integrative Treatment Development Program*, e.g., NIDA, <http://grants.nih.gov/grants/guide/pa-files/PA-13-077.html>), which detail how to test efficacy, conduct clinical trials, examine mechanisms of behavioral change, determine dose-response, optimize combinations, and/or ascertain the best sequencing of behavioral interventions. This program has conceptualized therapy development research with a model consisting of six stages for transferring the conventional pharmaceutical clinical study model to behavioral and integrative treatment programs. This stage model is very useful for translating Qigong practice into an effective clinical program and should be consulted in clinical study preparation.

Of course standardization and an operational manual will not eliminate individualized instruction and individual adaptations; rather, researchers must put individualized instructions and alternatives into the manual so that clinicians can easily adapt the practice according to the needs of particular populations. When applying Integrative Meditation (IM) to the treatment of co-occurring

anxiety disorders in heroin addicts, we developed manuals for both therapists and patients and included many simple breathing and guided imagery techniques for daily relaxation and anxiety management. However, since guided imagery will be slightly different for different patients, we included specific instructions as to which type of imagery works best for particular conditions such as hypertension, headache, low back pain, and worry. Individualized instructions with immediate application to their daily lives make patients more likely to practice IM at home.

5. Quality Control: Monitoring Compliance

After choosing the appropriate Qigong form, conducting a feasibility study, standardizing the therapy, developing a manual, designing a compatible control group, and getting ready to conduct the RCT, the next challenge is quality control during the trial: how can the investigator tell that participants are following instructions and practicing correctly? Monitoring such compliance is far more complicated than counting pills or asking participants to keep a diary as typically done in pharmaceutical trials.

It is good practice to monitor meditation time and days of practice after training or instruction. Diaries or weekly surveys with timeline are widely used in this type of clinical trial. But the quality of Qigong practice is not merely about time or frequency of practice: state of mind and depth of meditation make a difference in outcome. We have no standard way to measure the depth of the Qigong state at this moment, although many scientists have tried to develop physiological measures to assess quality of practice. I incorporate the following measures when monitoring practice quality:

- Frequency of falling asleep during meditation
- Level of relaxation during practice
- Degree of peace and tranquility felt during practice
- Ability to follow the flow and to feel at one with oneself during practice
- Ability to let go, detach, become unaware of breathing and body posture
- Degree of fatigue or relaxation after practice

The ability to feel at one with oneself or enter a deep meditation state is probably key to a positive clinical outcome in Qigong therapy. To monitor this state in a clinical study, it might be feasible to measure physiological changes during meditation or Qigong practice to quantify the degree of changes, but this necessitates a pre-determined agreement as to what is really being measured. Professor Liu at the Beijing University of Chinese Medicine has developed a special technique to measure the internal and external quality of meditation. He calls it “two-way layout, correlated detections, and mutual paraphrasing” (双向设计、关联检测、相互释义) and has used it in clinical studies on Qigong practice. It has three important components:

- Two-way layout encompasses a subjective report of mental and physical state and an objective offset of physiological measures. Just as an instrument needs meticulous adjustment before use, subjects need collective training before exercise or study in order to coordinate their actions and internal operations with those of the other practitioners in so far as possible. For instance, in an experiment on mental focus, the instruction would involve showing subjects the object of focus, explaining the difference between tranquility, concentration, and mental focus, and teaching the subjects how to achieve each of these three states. As an instrument test requires detectors, so do internal human activities; these will form the content and steps of the study design. It is only the subjects themselves who can realize and evaluate these internal states, so internal detectors are subjective, although they must be standardized before the study.
- Correlated Detection (or measurement) refers to the simultaneous operation of objective, external indicators or measures and subjective, internal operational indicators or assessments during a study. This is done in two steps. (1) Every internal measure must correspond to an external one. (2) External detection does not start until its corresponding internal operation occurs; this may be signaled by the practitioner or by predetermined timing.
- Mutual Paraphrasing means that the internal and external indicators reflect each other. In two-way layout and mutual paraphrasing, a change in an external measure is thought to be caused by its corresponding internal operation; the internal operation is the moving power of the external change. The subjective operation has its objective expression, and the objective indicator points to a subjective feeling or change in that feeling. Thus changes in internal states can be distinguished by changes in external indicators, and the value of an internal change can be calculated through the external indicator.

In order to conduct effective research using two-way layout, the scientist must be a good Qigong practitioner. Traditionally, most scientists studying Qigong have been good at physiological measurement and psychological assessment, but not good at Qigong or meditation and thus are incapable of designing the internal stages of Qigong practice. Without Qigong training and practice, it would be difficult to produce valid and measurable steps that correspond to Qigong states and depth of meditation. Thus it is important to encourage scientists studying mind-body medicine to practice the modality themselves. This is becoming a trend in the United States, and as scientists and clinicians become practitioners of mindfulness meditation, clinical study designs for Qigong and meditation will greatly improve.

6. *“Dosage” Could Be the Key; Intensity of Practice and Efficacy*

The appropriate amount of practice in order to achieve expected or significant health improvements during the period of study is another major challenge in research design. Some medical Qigong texts recommend length of a treatment cycle for some classic Qigong forms (Liu & Chen 2010),

but these are based on experience, not clinical trial data, and were designed for ancient Chinese patients. It is unclear whether they are appropriate for other ethnicities or for modern peoples. The rule in Qigong practice is “practice is better than non-practice, daily practice is better than intermittent practice, and the more the better.” However, in setting up a clinical study we attempt to predict the minimum “dosage” of practice that will produce the desired benefits. That most studies on Qigong produce negative outcomes, or no significant difference from control, might be related to the fact that the dosage was too low to achieve the significant improvement.

For example, in an RCT by Astin and his colleagues (2003) on the efficacy of mindfulness meditation plus Qigong movement therapy for treating fibromyalgia (FM), both the treatment group and the education control group significantly improved after 24 weeks without significant differences between them. The researchers concluded that “there was no evidence that the multimodal mind-body intervention for FM was superior to education and support as a treatment option.” The Qigong form used in this study was developed, in a pilot study, specifically for patients with FM, but the dosage of Qigong practice was about 60 minutes a week without mention of homework or daily practice. This might not be enough for daily stress management that restores body and mind to balance and harmony. Anecdotally, I have two friends who cured their FM with intensive Qigong practice. Daily practice, even for only 15 or 20 minutes, might be key for patients who need Qigong for therapy not just for general health.

How much practice does it take to see significant clinical improvement? There is no standard answer to this question, which depends on the Qigong form and the particular health concern. I have observed that a 20-minute section of “lowering blood pressure Qigong” can make an immediate, short term change of about 10 mmHg in patients with hypertension. However, it might take 25 minutes a day for months to maintain that result. The same might be true for anxiety; 20 minutes of quality abdominal breathing can significantly reduce anxiety or control a panic state, but reduction or remission in diagnosed anxiety disorders will probably require daily practice for some months. Again, ascertaining the mechanisms of Qigong healing in a pilot trial will greatly help researchers identify the appropriate dosage of Qigong practice.

According to medical Qigong classical literature, if Qigong practice is for treating a specific health condition, not just for stress management or health maintenance, daily practice is usually required. Twenty minutes a day is commonly required for many Qigong forms in health maintenance; more practice is needed for chronic conditions such as FM or cancer. When I learned Daoist Inner elixir Qigong, my teacher asked me to practice at least 45 minutes twice a day in order to achieve the expected physical and spiritual outcomes within 100 days. That was just to cultivate Qi through the so-called microcosmic cycle, not to treat a disease. Of course, at this intensity most illness would disappear after 100 days of practice.

It is common to encounter dilemmas when choosing between feasibility and efficacy. If daily or 4-5 times a week practice is unfeasible for a given population, Qigong might not be the appropriate therapy for an RCT. Without the appropriate dosage – frequency and amount of practice – the practice

will not produce the expected clinical outcomes and should not be selected for a formal clinical trial. However, if the patient population is large enough, the researcher may include willingness to engage in daily practice as a recruitment criterion and offer Qigong therapy only to those who are willing to commit the time.

It is important to determine the appropriate dosage in an effective pilot study with key outcome assessments of different dosages before initiating an RCT. Some researchers have conducted pilot studies before an RCT but only to measure the significance of improvement from baseline, forgetting or ignoring possible placebo or unspecified effects due to other factors. For example, in RCTs on pain relief, the average placebo effect is a reduction of 30%. If Qigong practice does not reduce pain by more than 30% in a pilot observation, an RCT would be pointless. For some conditions related to stress, irritable Bowel Syndrome for example, the reported placebo effect is on average about 38% (Ford & Moayyedi 2010) to 42%. If the investigator does not achieve 45% or more improvement in pilot trial, the Qigong dosage is not yet appropriate for an RCT.

7. Simple Intervention vs. Life-style Change

So far most published reports on Qigong practice have been on Qigong intervention alone or combined with other therapies to treat a specific health condition such as hypertension, pain, sleeping disorder or anxiety, and focus on clinical outcomes for that condition during a specified period of study. However, most Qigong was not created as a therapy but as a daily wellness practice that helps practitioners achieve mind-body balance, harmony in life, or reach higher spirituality. If you ask a Qigong practitioner why they practice Qigong daily and what they have gained from the practice, you will get answers such as a more relaxed, harmonious state of mind and body; noticeable reduction in prior ailments; reduction in stress; increased resistance to illness; heightened sensitivity to the body's internal organs and the ability to regulate health and vitality. In other words, Qigong practice is more a prevention than an intervention and more a life style than a clinical therapy. Clinical investigators should take this historical perspective into consideration when deciding practice intensity, study length, and outcome measurements.

There are a number of case reports on the simultaneous remission of multiple disorders and unexpected healing outcomes after intensive Qigong practice (Chen & Turner, 2004; He & Chen 2002). These might be difficult to document in an RCT. However, the RCT should not be the only model for studying the health benefits of Qigong therapy. Many other models of clinical observation and documentation may be used, as has been done in Chinese medicine over the past thousand years. If researchers start thinking of Qigong practice as a means of life-style change or a way of life that offers self healing, Qigong research study design would be very different.

I came across a longitudinal survey study on annual healthcare spending conducted by the Xiangtan City Department of Health and Department of Senior Cadres. The study followed 500 senior government cadres, who practiced Qigong on a regular basis, between 1992 and 1995 while their

health care was fully paid by a government health program. To the investigators' surprise, instead of observing an increased annual spending in health care over time as customary for most seniors in that age group, they found a significant decrease, not just a small one but an average reduction in annual spending of 83%: 232 cadres (46%) incurred no medical cost at all except for regular physical exams. That was an astonishing finding, and it showed health benefits and improvement in quality of life from Qigong practice through a study with a very simple research design.

To measure changes in life style, quality of life, or health care expenditure, the research period must be considerable and the outcome assessments must cover multiple aspects. A standard clinical trial with a three-six month follow up might not be long enough to observe true benefits and key outcomes. We must engage in more practical and more appropriate research designs such as longitudinal cohort, community, case-matched control, and combined-design study.

Qigong has long been a self-care, mind-body therapy and life-nurturing practice in China for thousands of years. Because many unique methodological issues arise when we conduct clinical research on Qigong as a therapy, we must learn more about the characteristics of Qigong forms and their underlying mechanisms before we can design valid RCTs that determine their feasibility and efficacy for specific health conditions. More importantly, Qigong practice is a way of life and a comprehensive way to enrich the physical, mental, and spiritual well-being of its practitioners. Thus the conventional RCT might not be the best means for studying the health benefits of Qigong. Modern research on Qigong and mind-body medicine should reflect the unique features of the therapies and document the true benefits of integrative practice for mind, body, and spirit. As pointed out in the Yellow Emperor's Internal Classic, "Remain detached and empty-minded so genuine Qi will flow easily; keep essence-spirit within and no illness will arise."

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