



**P R O V I D E**

ImPROving cross-sectoral collaboration between primary and psychosocial care:  
An implementation study on VIDEo consultations (PROVIDE)

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# STAGE I – INTERVENTION MANUAL

## FOR THE PROVIDE-B FEASIBILITY STUDY

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## A. Overview, description, and rationale

**General description of the approach.** Web-based, real-time video consultations involving a live two-way interactive video to a primary care practice between mental health specialists (MHS) and patients are increasingly considered as an alternative to conventional face-to-face integrated care models [1-3]. The PROVIDE project (ImPROving cross-sectoral collaboration between primary and psychosocial care: An implementation study on VIDEo consultations; <https://www.provide-project.de/ziel-konzept/?lang=en>) aims to define, tailor, and evaluate such a technology-facilitated intervention in primary care. The main components of the intervention are: specialised clinical evaluation (incl. systematic assessment/diagnostics), brief therapy (including general support, brief psychotherapy, and psychopharmacology), and, if required, triage to specialist mental health services. The PROVIDE intervention is a first-line intervention introducing videoconferencing communicating technology as an integral part of general health care. The intervention targets patients with depression and anxiety disorders as common mental health disorders which constitute the main remit of primary care and may be managed entirely within primary care [4].

**Background and rationale for the treatment.** Depression and anxiety disorders are two of the most common and disabling mental health conditions worldwide in adults and pose a substantial public health burden [5]. Most patients are treated in primary care, which has evolved as the crucial point of mental healthcare in many high-income countries [4], since fewer than one in ten patients with mental health problems in the community are actually seen and treated in specialist settings [6, 7]. However, a significant number of people suffering from mental health conditions, especially those with somatic comorbidities, do not receive adequate treatment [8]. On the one hand, primary care reimbursement systems apply few financial incentives for treating the increasing number of mental health problems more comprehensively (e.g., conventional fee-for-service payment regulations do not cover consulting with specialists that does not involve direct patient contact). In fact, primary care practices stick to tight schedules and visits are too time-limited to address complex mental health issues [9]. On the other hand, specialists are already busy with caseloads of patients or are simply not available, particularly in rural and underserved areas (so that in-person colocation of MHS cannot be realized

neither) [10]. In any case, rates of engagement with specialist mental health care are low overall (especially in older people) and despite the given barriers, most patients seek initial care for mental health complaints in primary care [11]. Hence, to address these supply-demand-imbalances, it is essential to develop care models that combine the easily accessible environment of primary care and the specialised expertise of MHS by leveraging technology to save travel and time [12].

***Theoretical mechanism of action.*** The PROVIDE intervention is a targeted primary care-based mental health service combines elements of the collaborative care and consultation-liaison models [4]. We hypothesize that the PROVIDE intervention will exert its effects by making MHS virtually available in the less stigmatizing primary care setting that is easily accessible and familiar to the patient. The intervention aims to “capitalize on the strengths of both systems: the primary care provider’s connection with, history with, and comprehensive knowledge of the patient, combined with the mental health expert’s skill at diagnosis and treatment and capacity for longer or more frequent visits” [12]. Indeed, there is some evidence that of higher patient engagement in integrated care [13].

In the PROVIDE intervention, patients will receive specialised support and, if needed, triage at the first point of contact of entry into the health care system. The intervention includes three core processes (“active ingredients”) for effective primary care-based mental health care, namely systematic diagnosis plus proactive monitoring using validated clinical rating scales, the establishment of an effective working alliance, and a stepped-care algorithm within integrated care adjusting treatments based on clinical outcomes [12]. If indicated, the PROVIDE intervention also includes brief psychological therapy that works with interpersonal dynamics and that has been shown to confer additional benefit [14, 15]. Finally, aiming at high continuity of care in a primary care system acting as gatekeeper to off-site specialist services, the PROVIDE intervention will tailor service provision to the patient’s central problems and consequently increase treatment uptake, acceptability, and retention even in hard-to-serve populations.

## B. Conception of the disorder

**Depression in primary care.** Depressive symptoms cover “a continuum from everyday sadness to suicidal depression” and very often occur with anxiety [16]. Indeed, anxiety symptoms indicate poorer outcomes for depression. The diagnosis of depression is based on the presence of at least five out of nine symptoms as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-5). The Patient Health Questionnaire 9 (PHQ-9; available from <http://phqscreeners.com>) measures these nine symptoms as follows:

*Low mood or loss of interest and pleasure present most of every day for at least two weeks, plus four out of the seven following symptoms which are associated with clinically significant distress or impairment in social, occupational or other important areas of life:*

<i>change in sleep pattern</i>	<i>change in appetite or weight</i>
<i>poor energy, tiredness</i>	<i>poor concentration, forgetfulness</i>
<i>guilt, worthlessness</i>	<i>agitation/retardation</i>
<i>suicidal ideas</i>	

While subthreshold/minor depression can be addressed with non-specific support and monitoring of symptoms, a higher number of symptoms, a significant impairment of functioning and/or persistent symptoms are indicators for the need of active treatment. Kendrick et al. underscore that “even if a depressive episode is ‘understandable’ in the patient’s context, this should not mean they should be denied psychological or drug treatment which might help them” [16]. At any point of care delivery, both findings from clinical rating scales (PHQ-9 and/or GAD-7) and the degree of interference with daily activities caused by the patient’s symptoms should be accounted for in clinical decision-making.

Depression is associated with a combination of genetic, environmental, biological, cultural, and psychological factors. Because of that multifactorial aetiology of depression, the general practitioner (GP) often is the first-contact access for the need for mental health care. In fact, most patients with depression are treated entirely by their GP [17]. Depression also has significant bidirectional relations with physical health conditions with a clear dose-response relationship between the number of long-

term physical conditions and depressive symptoms [18]. Interactions between depression and chronic conditions are known to have large negative effects on functional disability of patients [19]. Current thinking acknowledges that depression develops as the result of complex gene-environment interactions with economic disadvantage, social isolation, significant loss, and violence or abuse as the most significant social stressors. Family or personal history of depression and alterations in serotonergic and dopaminergic signalling pathways are also associated with depression.

Recognising depression in the setting of primary care is somewhat difficult, particularly in patients with multiple comorbidities [7, 20] and/or somatic or nonspecific complaints [21]. Recommendations on formal screening programmes differ between countries. In contrast to the US, where a routinely conducted screening in the adult population in primary care is recommended by the US Preventive Services Task Force (USPSTF) [22], similar organizations in the UK (UK National Screening Committee) and Germany (Institute for Quality and Efficiency in Health Care) do not recommend such screening assessments in primary care due to the lack of evidence for the expected benefit [23, 24]. Indeed, the number of false-positive responses is larger than the number of true-positive responses, due to the relatively low prevalence (< 10%) of major depression among the primary care population [16].

The treatment of depression provided by GPs is only rarely consistent with existing guidelines and often limited to prescribing antidepressants [25, 26], while psychotherapy alone is often very effective in mild to moderate depression. However, one valuable aspect in GP centred mental health care is the provision of long-term person- rather than disease-focused care [27]. Knowing the patient and his or her medical history for a long time, sometimes for a whole life, brings the GP in a unique position to address the patient's needs adequately.

**Anxiety in primary care.** Anxiety disorders (anxiety mixed with depression, specific phobias, generalized anxiety, post-traumatic stress disorder, obsessive-compulsive disorder, panic without agoraphobia, social anxiety disorder, and agoraphobia) are the most common mental health conditions in community settings [28]. Specifically, anxiety mixed with depression is the commonest form of anxiety disorder. Abnormal anxiety occurs when the level of anxiety is “out of proportion to the level

of threat or when there are symptoms that are unacceptable regardless of the level of threat, including panic attacks, severe physical symptoms, and abnormal beliefs such as fear of sudden death” [29].

GPs tend to not recognise anxiety symptoms, as patients may not complain of them overtly [11] and in turn, GPs retain their focus on physical symptoms. Rather people present with unspecific symptoms such as fatigue, insomnia, chronic pain, palpitations, chest pain, flushing, sweating, faintness, shortness of breath, gastrointestinal symptoms, dizziness, headache, and muscle pains [29]. Formal screening is not justified for anxiety disorders neither, but case-finding should be considered for groups at high-risk (people presenting with non-specific abdominal pain, chest pain, tachypnoea, and breathlessness). Since distinguishing depression from anxiety poses some challenge, the following table lists the prototypical differences [29, 30]:

<b>Anxiety</b> “Being helpless”	<b>Depression</b> “Being hopeless”
Hypervigilance	Low mood
Agoraphobia	Anhedonia
Compulsive behaviours	Weight gain/loss
	Loss of interest
	Suicidal ideation
Insomnia	
Fear	
Poor concentration	
Fatigue	

The current under-recognition of anxiety disorders leads to inadequate treatment in primary care which is reflected in a lack of planned follow-up and monitoring of the patients [31].

### C. Treatment goals

**Specification/determination of treatment goals.** The primary goals of the PROVIDE intervention consist of a) an accurate diagnosis and case formulation for the individual patient and b) the reduction of the depressive or anxious symptom load (as measured in the PHQ-9, and/or Generalized Anxiety Disorder Scale, GAD-7). Accounting for the fact that the inability to function is largely a subjective experience, the secondary goals and their prioritization are negotiated between the patient and the MHS. If required, the MHS prioritizes the engagement of patients with specialised services.

**Evaluation of primary and secondary goals.** As for the primary goals, the MHS explicitly states that the goal of treatment is symptom reduction and, ultimately, symptom remission. Nevertheless, the MHS follows a patient-centred approach as opposed to a disease-based approach and therefore acknowledge the uncertainty for highly ambivalent patients, which are more common in primary care practice compared to specialised services. Symptom development will be measured applying the PHQ-9 and GAD-7 after the third session (approximately four to five weeks after enrolment) and four months after enrolment. With respect to the secondary goals, the progress towards the patient's goals is evaluated on a session-by-session basis.

### D. Contrasts to other approaches

**Similar approaches.** The PROVIDE intervention is fairly similar to conventional consultation-liaison models in primary care mental health [32] and the collaborative care model [33, 34], which both constitute a trade-off between increasing involvement of the primary care clinician on the one hand and increasing involvement of the MHS on the other hand [4]. Both models, as the PROVIDE intervention, target well defined disorders that are associated with some degree of disability, but for which effective treatments are available. Nevertheless, consultation-liaison or collaborative care services rarely employ video technology, and collaborative care specifically includes the addition of quasi-specialist case manager who liaises general practitioners with specialists.

**Dissimilar approaches.** From the technological perspective, the synchronous PROVIDE intervention resides at the upper end of the e-behavioural health continuum of interventions for primary care [3]. In contrast, following Hilty et al. [3], low to moderate intensity technology models comprise website information, support/chat groups, social media, formal educational materials, resources for self-directed assessment, resources for self-care decision-making, assisted self-care assessment and decision-making, asynchronous, between-session patient-clinician contact (e.g., mobile health, app text, e-mail). However, the PROVIDE intervention is somewhat less intensive compared to hybrid care which includes either in-person care and an e-option or telepsychiatry and an e-option [35].

### **E. Specification of defining interventions**

The PROVIDE intervention follows a transdiagnostic treatment approach for emotional disorders (depression and anxiety), for which various meta-analyses have shown the efficacy compared to control conditions on measures of overall anxiety, disorder-specific anxiety, and depression [36-41]. Specifically, the intervention combines elements from problem-solving therapy (PST), which has been shown to yield moderate effects in alleviating depression and anxiety in primary care [42], with transdiagnostic psychodynamic treatment elements [43-46]. Psychodynamic elements following a relationship focus and interpersonal understanding are added to foster the working alliance. Indeed, establishing a trusting working alliance has been promoted as a crucial element of manuals achieving high acceptability in both patients and clinicians [47]. The intervention is conducted in line with “Best Practices in Videoconferencing-Based Telemental Health” issued by the American Psychiatric Association (APA) and the American Telemedicine Association (ATA) [48].

**Unique and essential elements.** First, over the course of the entire intervention, MHSs are strongly encouraged to aim for an in-depth understanding of the psychological elements at play and focus the specific “conflictual area to reach an understanding of the psychopathological picture manifesting as a crisis” [43]. Second, MHSs should generally tend to facilitate the affective experience/expression, since this is consistently related to more patients improving [49]. This can be achieved by urging

patient to practice “emotional mindfulness” as a way of identifying, attending to, and being present with emotional experience manifested in physical correlates [44].

At any given point, patients exhibiting suicidal ideas and plans and/or psychotic symptoms should receive an urgent referral to off-site specialist mental health services.

***Essential but not unique elements.*** When initiating brief therapy, MHSs are advised to recognise and relinquish maladaptive defences (defense restructuring), desensitize affects through exposure to conflicted feelings (affect restructuring), and, most importantly, improve the sense of self and relationship with others (self/other restructuring) [44].

***Recommended elements.*** If a solid working alliance can be established and a clear conflictual area can be identified, MHSs are recommended to take an active role and to “selectively [disregard] any information that the patient may provide him, which falls outside the main area agreed on and by working through the central conflictual area in the psychic life of the patient” [31]. In addition, MHSs should attempt to support patients in experiencing and adaptively expressing previously avoided feelings.

***Proscribed elements.*** First, at this point, there is no evidence for contraindications to use video consultations in mental health conditions, unless the patient refuses treatment or actively poses a threat to herself/himself and/or others. However, the use of video consultations should be critically evaluated in patients with psychotic symptoms and in elderly patients with sensory deficits and/or cognitive impairment. Second, given the brevity of the intervention, the MHS must not enforce regression of the patient (e.g., by not setting goals). At any rate, the MHS should be closely monitor the course of the intervention for countertherapeutic interventions. Finally, the MHS should refrain from criticizing the general practitioner whatever she/he has been doing, because one overall aim is to foster the relationship between her/him and the patient.

## F. Session-by-session content

**Preparation of video consultations.** The PROVIDE intervention is conducted in individual, synchronous one-to-one video consultations which will be conducted on a secure (i.e. encrypted), web-based videoconferencing platform on a subscription basis (provided by arztkonsultation ak GmbH, Schwerin, Germany; <https://arztkonsultation.de>). The certificate of data privacy and protection can be found here: <https://arztkonsultation.de/datenschutz-zertifizierung.html>.

The MHS and the patient may use a desktop PC, a laptop, a tablet, or – less ideally – a smartphone for the video consultations. A modern webcam (> 720p) and a microphone are required. To optimize audio (e.g., to prevent an echo effect), the use of a headset and turning up the volume only to mid-level is recommended. The broadband connection should be stable (bandwidth: download > 4 Mbit/s, upload > 1 Mbit/s). The following browsers are supported: Google Chrome (strongly recommended), Mozilla Firefox, Opera, and Safari (Microsoft Internet Explorer and Edge are currently not supported). The technical requirements will be checked whenever a new session is initiated.

To reduce the gaze angle and enhance the sense of eye contact with the patient, the MHS should ideally place the webcam on a PC system as close as possible to the image of the patient on the screen. To evaluate her/his online presence, the MHS may routinely use the “picture in picture” function on his/her screen. To avoid distraction, this function should however be deactivated on the patient’s side. The MHS should avoid dressing in white and green colours; patterns on ties, blazers, blouses, scarves, and jewellery should be small [50].

The room designated for the video consultations should ensure maximum privacy (no thin walls); no third person should enter the room while the consultation is on-going. When preparing the room, there should be no bright light behind the head of the MHS, doors and curtains should be closed, and the main room lights should be turned on as brightly as possible. The MHS should mind the background and avoid potentially divisive (e.g., political, religious) background décor [50]. To prevent privacy breaches, all windows and doors must be shut during the consultation.

To maintain good visual positioning, the MHS should be well centred (eyes two-thirds of the way up the screen) and taking up about half of the total screen space. The MHS should be approximately one meter away from the screen when using a desktop PC and half a meter away from the screen when using a laptop or tablet. Notably, people tend to raise their voice during videoconferencing. This should generally be avoided to minimize irritations for the patient. When the patient and the MHS talk over another, the MHS should pause and signal nonverbally that she/he is listening (e.g. by pointing to her/his ear).

***Procedures in every consultation.*** At the beginning of each consultation, the MHS should clarify the exact location of the patient and together with the patient make sure that they both know exactly who is involved in the video consultation. Everyone should always be on screen. Additionally, the MHS inform the patient about the remaining number of consultations. At the end of each consultation, the MHS should always consider asking the patient what her/his experience was and if she/he is comfortable enough to continue treatment in this way. Finally, the patient and the MHS consider scheduling a follow-up consultation.

After each consultation, the MHS must inform the primary care practice team about the scheduled follow-up consultation, if applicable. The MHS is also asked to compile template-driven follow-up notes which should be written in a format easily understandable by other doctors. The notes may be structured in the subjective-objective-assessment-plan (SOAP) format.

***Contingency procedures/safety plan.*** The MHS should always be aware of technical limitations such as nonmuting, poor visual definition, impaired audio, and speech delay. In case the broadband connection is instable, or the quality of audio is poor, the MHS should quickly switch to an alternative mode of communication (primarily mobile phone or landline phone of the primary care practice) to avoid misinterpretations and frustration with the technology [50]. With respect to acute crises (e.g., suicidal ideation, medical emergency, violence), the MHS should have the contact of a patient's significant other (physically close to the patient) at hand and should always be aware of the nearest places of safety and emergency care. Specifically, according to Yellowlees & Shore [50], the safety plan should include:

- the patient's physical address and current working telephone number
- a working telephone number for emergency personnel/services in the patient's location
- a contingency plan for reconnecting with the patient if a technical disruption occurs

***Initial consultation – Getting familiar with the telemental health setting, building a working alliance, and specialised diagnostics.*** First, the MHS should introduce herself/himself (an example can be found here: <https://www.youtube.com/watch?v=zWBJDj9owv0>), ask the patient about her/his working knowledge of videoconferencing and address any questions on the technical aspects and/or the security of the transmission. The MHS should then consider asking an icebreaker question (e.g., “How do you feel in the room you are in?”). Second, to establish rapport, the patient is socialized for the intervention by inviting her/him to talk freely about the central problem (conflictual area). The MHS starts to take a detailed history and aim to understand the patient's concerns. Third, the MHS informs the patient about the condition (depression and/or anxiety), its adaptive function and available treatment options [45]. Fourth, the MHS starts to engage in motivating the patient to expect that change is possible. Finally, practical arrangements for the intervention are made (maximum number of five sessions, duration of sessions, estimated duration of the entire intervention, personal phone number in the event of a technical breakdown or clinical emergency, arrangements for vacations, cancelled sessions, and patient non-attendance). It is recommended to set up phone appointments at specific time slots for potential between-consultation requests. During the entire session, the MHS gathers diagnostic information, e.g., through probing or applying established psychometric instruments, to derive a case formulation. For case formulation, the core conflictual relationship theme method may be used [45, 46, 51].

***Consultation 2 – Defining/clarifying the central problem, goal setting, and “emotional mindfulness”.*** While further exploring the central problem and clarifying the patient's motivation for taking the video consultations, the MHS takes an empathic position and interprets the patient's ambivalence between changing and remaining. To resolve some of the ambivalence, the MHS may consider motivational interviewing techniques (e.g., in patients with comorbid substance use disorders). Eventually, realistic (achievable) treatment goals are discussed, that is the changes the

patient aims for. Goals should not only refer to symptom reduction, but also to interpersonal relationships [46]. The MHS signals her/his support for the patient's wish to achieve the goals, notes them down in a shared longitudinal care plan, and asks the patient to practice "emotional mindfulness" until the next session and pay extra attention to physical responses while doing so [45]. The MHS may consider inviting the patient's family/significant other(s) for the third consultation.

**Consultation 3 – Maximized effort to support patient in expressing her/his (avoided) affects.** At this point, the MHS maximizes her/his effort in supporting patient with experiencing and expressing her/his (avoided) affects. Ideally, the patient's narrative and the related affects can be linked to the conflictual area and more adaptive responses can be fostered through defense, affect, and/or self restructuring. Against the background of dysfunctional relationship patterns, the patient and the MHS will generate and negotiate realistic solutions according to the preferences of the patient. At this point the latest, the MHS should ask herself/himself whether the patient will need further treatment, i.e. a referral to social services, specialist care and/or other community resources. Indications for referral to off-site specialist mental health services (e.g., psychotherapy, day clinics, or inpatient care) are [16]:

- recurrent episode within one year of last episode
- patient or relatives request referral
- self-neglect
- postnatal depression
- suicidal ideas and plans (urgent referral)
- psychotic symptoms (urgent referral)

During the entire session, the MHS identifies and highlights any potential resources of social support for the patient. If applicable, the MHS also activates health-promoting behaviour (sleep hygiene, eating diary, relaxation etc.).

After the third consultation, the study team will conduct a psychometric assessment using the PHQ-9 and GAD-7 to monitor the progress of the patient. Results will then be sent to the MHS.

**Consultation 4 – Empowering the patient and deciding on referral to specialist treatment.** The initiation and implementation of the discussed solutions will be evaluated. The MHS empowers the patient to take an active role in the treatment and pays immediate attention to any medical, legal, and/or family crises. While the MHS provides direct support in tackling with the crises pragmatically, she/he adheres to the discussion of relationship conflicts [46]. If the patient can be stabilised, the MHS will empathically address the interactional patterns associated with the crisis. Eventually, the patient and the MHS will decide on any referrals to specialist treatment or community resources. In doing so, the MHS will anticipate potential care gaps and consider the degree of interference with daily activities caused by the patient's symptoms along with PHQ-9 (1-4 points: no need for action, 5-9 points: monitor for any deterioration, 10 or greater: consider active treatment) and/or GAD-7 scores obtained after the third consultation. During the entire session, the MHS again highlights any potential resources of social support for the patient. If applicable, the MHS also activates health-promoting behaviour (sleep hygiene, eating diary, relaxation etc.).

**Final consultation – Termination, review, relapse prevention, and, if applicable, outlook to next treatment step/referral.** Patient and MHS review what they have done, thoroughly discuss steps to prevent relapses and, if applicable, the MHS will provide an outlook to the next treatment step which may or may not include referral to specialist mental health services.

After the final session, the MHS will compile a one-page case summary including potential recommendations for the general practitioner. This systematic feedback, on which, if needed, further clarifications on follow-up procedures between the GP and the MHS can be based, will be attached to the medical record in the primary care practice.

## **G. General format**

**Format for delivery.** Apart from the video consultations, there are no additional in-person consultations between the patient and the MHS. If needed, the MHS may also invite the patient's family/significant others to attend one or more video consultations together with the patient. To

provide a treatment process as close as possible to real-world conditions, patients are permitted to reach out to their GP whenever necessary. GPs may prescribe psychopharmacological treatment either at their own discretion or following a recommendation from the MHS.

All MHSs receive group supervision on a weekly basis. The supervisor is a consultant in psychiatry and psychosomatic medicine with extensive experience in consultation-liaison psychiatry and psychotherapy.

**Frequency and intensity of video consultations.** The intervention consists of up to five video consultations, lasting 50 minutes. The total number of sessions the patient receives depends on her/his individual needs and the discretion of the MHS. The video consultations should be scheduled in biweekly intervals, but flexibility in scheduling video consultations is encouraged whenever necessary (e.g., due to crises or vacations). Assuming a biweekly schedule, the intervention will cover up to five consultations over ten weeks for each patient. The MHS will schedule all consultations together with patients and inform the primary care practice about all appointments.

**Flexibility in content.** The PROVIDE intervention allows for flexible sequencing of the content areas of the respective consultations according to the patient's needs. However, the MHS should always bear in mind the brevity of the intervention as such and work towards stabilisation and, if needed, triage the patient to off-site specialist mental health services.

**Session format.** Each video consultation lasts 50 minutes. Taking into account the outline of the consultations, the MHS sets the agenda for each session together with the patient. At the end of each session, the MHS may give a brief summary of the session content. Furthermore, the patient and the MHS consider arranging a follow-up consultation about which the primary care practice team will be informed by the MHS.

**Level of structure.** For each consultation, the level of structure depends on the observed symptom load. The more the patient seems to be distressed, the more the MHS should proactively structure the consultation. As a basic guidance, the MHS should generally let the patient talk more than the MHS.

**Extra-session tasks.** To facilitate behaviour change, the MHS may request the patient to conduct extra-session tasks (e.g. homework for practising “emotional mindfulness”). Whenever homework is applied, in the following consultation, the MHS should evaluate how the patient dealt with it and validate her/him, if she/he succeeded. If the patient fails to complete an assignment, the MHS should mindfully explore the underlying barriers and, ideally, relate them to the conflictual areas of the patient.

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